MEDICARE REGULATORY AND CONTRACTING REFORM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

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MEDICARE REGULATORY AND CONTRACTING REFORM

THURSDAY, FEBRUARY 13, 2003

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 12:10 p.m., in room B–318 Rayburn House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
February 06, 2003
HL–1

CONTACT: (202) 225–1721

Johnson Announces Hearing on Medicare Regulatory and Contracting Reform

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on the progress of regulatory reform since House passage of the bipartisan "Medicare Regulatory and Contracting Reform Act of 2001." **The hearing will take place on Thursday, February 13, 2003, room B–318 Rayburn House Office Building, beginning at 12:00 noon.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include the Honorable Tom Scully, Administrator of the Centers for Medicare and Medicaid Services (CMS); Dr. Douglas L. Wood from the Mayo Clinic, Chairman of the Secretary's Advisory Committee on Regulatory Reform; and representatives from provider and beneficiary groups. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

On August 2, 2001, Chairman Nancy Johnson and Ranking Member Pete Stark (D–CA), joined by every Member of the Subcommittee, introduced H.R. 2768, the "Medicare Regulatory and Contracting Reform Act of 2001," the first major bipartisan Medicare legislation developed by the Committee on Ways and Means in the 107th Congress. This package would have extended important regulatory relief to our nation's health care providers and modernized Medicare's contracting processes, while protecting the program and taxpayers from potential fraud and abuse. A modified version of the bill, H.R. 3391, passed the House unanimously on December 4, 2001. Additionally, most of the provisions were included in H.R. 4954, the "Medicare Modernization and Prescription Drug Act of 2002," which passed the House on June 28, 2002.

The Medicare Regulatory and Contracting Reform Act would improve provider compliance with Medicare policies through provider education and technical assistance. It would create time frames for issuance of new regulations, prohibit retroactive application of the issuance of new regulations, improve provider appeals, reform recovery of overpayments, and improve new technology integration. The Administration has adopted a number of the provisions in the Act, such as the process for prepayment review of claims and giving notices to beneficiaries and providers when a claim is rejected due to a local medical review policy.

The Secretary also has taken on the important task of bringing together a task force comprised of beneficiaries and providers, as well as experts from the Office of the Secretary, the Centers for Medicare and Medicaid Services, and the Food and Drug Administration, to create the Secretary's Advisory Committee on Regulatory Reform. This task force focused on solutions that could be implemented immediately, and would reduce both obstacles to patients' access to care and the amount of time that doctors, nurses, and other providers spend on paperwork, which, in

turn, reduces time spent on patient care. The November report included 255 recommendations, 26 of which have already been implemented.

In announcing the hearing, Chairman Johnson stated, "Good, responsible professionals are frustrated by a system that seemingly emphasizes policing providers rather than helping them deliver better care to our seniors. Our bill was designed to refocus oversight, and we are making progress. We want health care providers to spend their time with patients, rather than filling out piles of paperwork, and we want to make it easier to be a Medicare provider. Program integrity must be protected—and so must the ability to deliver quality care."

FOCUS OF THE HEARING:

The hearing will give the Administration and other witnesses an opportunity to comment on the Medicare regulatory and contracting reform legislation passed by the House last Congress, and the Subcommittee's subsequent work on these issues. We will also hear from health care providers who would be affected by the proposed reforms in the legislation.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Due to the change in House mail policy, any person or organization wishing to submit a written statement for the printed record of the hearing should send it electronically to hearingclerks.waysandmeans@mail.house.gov, along with a fax copy to (202) 225–2610, by the close of business, Thursday February 27, 2003. Those filing written statements that wish to have their statements distributed to the press and interested public at the hearing should deliver their 200 copies to the Subcommittee on Health in room 1136 Longworth House Office Building, in an open and searchable package 48 hours before the hearing. The U.S. Capitol Police will refuse sealed-packaged deliveries to all House Office Buildings.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. Due to the change in House mail policy, all statements and any accompanying exhibits for printing must be submitted electronically to hearingclerks.waysandmeans@mail.house.gov, along with a fax copy to (202) 225–2610, in Word Perfect or MS Word format and MUST NOT exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. Any statements must include a list of all clients, persons, or organizations on whose behalf the witness appears. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at http://waysandmeans.house.gov/.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman JOHNSON. The hearing will convene. Today this Subcommittee holds the first hearing, our first hearing of the 108th Congress, to improve the operations of the Medicare program and reduce the regulatory burdens for seniors and Medicare providers.

In December 2001, we unanimously passed the bipartisan Medicare Regulatory and Contracting Reform Act, and we included most of its provisions in the Medicare Modernization and Prescription Drug Act of 2002, which passed the House in June of that year.

However, because the Senate did not act, regulatory and contracting reform is still before us. I might remind you, it would still be before us anyway because that bill was a start, not an end; but indeed, 2 years later, we start from the same point. If there is one thing I hope to accomplish this year, it is passage of a strong, thoughtful, Regulatory and Contracting Reform act. We certainly need it.

Medicare regulations consume more than 130,000 pages, three times the number of pages of the Tax Code and the tax regulations. This complexity has not only meant that Medicare answered, as the U.S. General Accounting Office (GAO) study from a couple of years ago showed the power of complexity to destroy a system, Medicare themselves answered 85 percent of the questions called in wrong or incompletely. They did not even look at whether the answers, where they were not actually wrong, were right and complete. These were boilerplate questions. These were the frequently asked questions. These were not complex or serious questions about a unique exception to the rule.

I make that point, and it is an old point, because this system is destroying itself. We are still increasing the problem.

If any of you have met with your nursing homes about compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), you will know that probably, as in my State, they all collaborated. They went through this long process, and now they are proud to say they have a notebook this thick about compliance with HIPAA.

If you are a nursing home administrator out in some rural area, some small town, or in some tough neighborhoods of a city, you have all you can do to keep quality care and nurses on the floor, and personnel out there and people cared for. You have payor regulations and all these other regulations, and now you have this notebook full.

The consequence of this system is going to be twofold. We need to understand it. We are going to destroy small providers. Think who cares for our seniors in the small cities and small towns across America, particularly in the rural areas: only small providers.

Health care has been a wonderful opportunity for women to become entrepreneurs because they are such skilled caregivers. Many of them care for family members, and then end up working for a home health agency. They then end up founding their own home health agency. We are destroying small business in the health service area if we continue down this track, because there will be no way that they can understand what is going on.

So, complexity and hyper-regulation, are barriers to the presence of health care providers in our small cities. It is a barrier to even

patients getting the care they need. It has become a barrier to quality developments.

I just want to thank each one of you that are giving testimony today, because some of you point out that relationship between the regulatory structure that we put on Medicare and our inability to improve quality. It is catastrophic that the only sector that is not in continuous improvement is health. With all the modern technology, new medicines, and all the new diagnostic techniques, we are not focused on continuous improvement. We are focused on silos and tiny silos; how much are we going to pay for this one thing?

You can't do continuous improvement, you can't improve quality, you can't keep small people in, and you can't give seniors access to health care if we don't do something about the regulatory burdens, and problems, and the complexity of all those things in Medicare.

Our first witness is the Administrator of the Centers for Medicare & Medicaid Services (CMS), Mr. Tom Scully. I want to thank you, Tom, for your responsiveness to our concerns, and for your initiative in this area. We have not been able to pass one dribble-drop of legislation, but you have moved forward aggressively in many of these areas. I commend you for this.

It could have been done before you. This has been a longstanding problem. You have taken the initiative to care about the regulatory complexity and burden of paperwork in Medicare. If you look at that study done by PriceWaterhouseCoopers for the American Hospital Association (AHA) a couple of years ago, there was no sector in which the paperwork time was not at least 50 percent of the patient care. In some sectors, it was 100 percent.

Pay attention. All of you out there have to stand up stronger. We have to work together more. We can't tolerate this.

I really commend you, Tom, for your aggressive leadership. I want to thank our first Chairman, Dr. Douglas wood, who is the Chair of the task force developed by Secretary Thompson and Tom Scully to go at this issue. I am very pleased he is here to testify. So, many of those testifying have the experience of that task force behind them, because they sat with people face to face and listened, which we have very little time to do. No one else does at all.

So, of the 255 recommendations, about 26 have been implemented and others are on the way. However, we have to move faster on that, and we have to see how we can work with CMS to move faster. I know they need legislation in some areas. It is not hard to make the case for the urgency of regulatory relief. If we can't hear it ourselves, we should not be sitting on this Subcommittee and we shouldn't be sitting in Congress, because our colleagues are now coming up to us.

So, I look forward to working with you all to not only pass the provisions in the bill that are needed, but to pass new provisions. I thank so many of you in your testimony for bringing new ideas to the table, and for using this exercise to unveil some of the underlying and more serious problems in the Medicare structure that are preventing us from moving forward on quality care systems. Mr. Stark.

[The opening statement of Chairman Johnson follows:]

Opening Statement of the Honorable Nancy L. Johnson, Chairman, and a Representative in Congress from the State of Connecticut

Today this Subcommittee holds its first hearing of the 108th Congress. We will take another look at improving the operations of the Medicare program and reducing the regulatory barriers for seniors and health care providers. In December 2001, we unanimously passed the bipartisan Medicare Regulatory and Contracting Reform Act. We included almost all these provisions in H.R. 4954, the Medicare Modernization and Prescription Drug Act of 2002, which passed the House in June 2002. Because the Senate did not act, regulatory and contracting reform is still before us. Today, Mr. Stark and I introduced the Medicare Regulatory and Contracting Reform Act of 2003, as a placeholder recognizing we will receive a lot of good suggestions at this hearing.

I hear about the need for regulatory reform from my constituents in Connecticut nearly every day. This is not surprising. Medicare regulations consume more than 130,000 pages. That's four times the number of IRS!

The purpose of this hearing is to re-examine the impact of regulatory burden on seniors, doctors, hospitals, nursing home and home health care agencies. As part of working to reduce regulatory burden, the Medicare Regulatory and Contracting Reform Act would improve provider compliance with Medicare by improving provider education and technical assistance. It would limit when new regulations could be issued, prohibit retroactive application of new regulations, improve provider appeals, change the recovery of overpayments, and improve new technology integration. The bill also will modernize the process for selecting Medicare administrative contractors through utilizing competition to attract the best the private sector has to offer.

Witnesses on our first panel—CMS Administrator Tom Scully and the task force chair Dr. Douglas Wood—will help us to understand the progress that has been made at the Department on providing regulatory relief. The Administration has adopted a number of the provisions in our bipartisan bill, such as the process for prepayment review of claims or giving notices to beneficiaries so that they understand when their claim is rejected due to a local medical review policy.

The Secretary of Health and Human Services established the Secretary's Advisory Committee on Regulatory Reform to focus on solutions that could be implemented immediately. The goal was to reduce obstacles to patients' access to care, and to reduce the amount of time that doctors, nurses, and other providers spend on paperwork, which, in turn, reduces time spent on patient care. The task force's November report included 255 recommendations, 26 of which have already been implemented.

However, despite the considerable progress you have made, too many health care providers are spending too much time struggling with paperwork rather than treating patients.

As we think about regulatory relief, however, it is vitally important that we not allow ourselves to believe that all regulation is inappropriate—in fact, patient protections, financial accountability standards, and operational guidance are a vital part of the Medicare program. So we will have to be sensitive to this balance between accountability and relief as we hear from our witnesses today and as we move forward in refining our legislation. But, I am confident that as we work together we will get it right. No matter what shape a modernized Medicare program ultimately takes, we all know that one of the most important measures of its success will be whether we can protect program integrity while ensuring that health care providers can focus on patients rather than paper.

Mr. STARK. It sure looks like we have our work cut out for us, Madam Chair.

Just a few things. I doubt if any of the testimony we hear today will do anything but put money in the pockets of providers, and I suspect we won't hear anything about helping the patients or the beneficiaries, who, if they had one or two Members on that commission you are talking about, they were lucky.

Also, if there was—I will spot you 140,000 pages of regulation—I don't know where you are picking them out, but if that is where they are, they are worth $100,000 a page a year. Because if we have had 14 billion of fraudulent payments a year, for every page you throw out you are costing $100,000 a year to the government.

So, I would say let us keep them and let us enforce some of the rules.

I have no interest myself in creating unnecessary paperwork, but I would suggest to you that—and to the witnesses who will testify—that I would like them to compare the paperwork they have to providers for wellpoint or Aetna or anybody else when they are collecting money, or BlueCross, at any place they are going to provide for non-Medicare beneficiaries or for Medicaid; in many States, just as much paperwork.

I am sure that my constituents would be overjoyed to hear that you want to reduce the paperwork on the hospitals and the doctors, but they would be 10 times more overjoyed if you all would come forth with a prescription drug plan, or a way to include the 40,000 uninsured in this country, or the children who you are cutting off the rolls this year with your welfare reform, because they are much more concerned about whether the hospitals and doctors will continue to get rich, and they would like to see our beneficiaries get some decent medical care.

I look forward to hearing from the witnesses as to what they are going to do to improve care for the beneficiaries. That would be an interesting bit of testimony.

Chairman JOHNSON. Thank you, Mr. Stark.

Mr. STARK. You are welcome.

Chairman JOHNSON. Mr. Scully.

STATEMENT OF THE HONORABLE THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

Mr. SCULLY. Thank you, Chairman Johnson and Congressman stark, for having me today to talk about Medicare's regulatory and contracting reform issues. The Committee has been incredibly supportive of everything we have been trying to do the last couple of years to streamline and improve Medicare. It is obviously a huge priority for the Administration and for the Department.

Before I walked over here, Secretary Thompson said to please tell you that this is probably his top priority to finally get this done. He said, Scully, you had better get contract reform done this year. So, I am under direct orders.

I certainly understand the scrutiny of our regulations. When I came here 2 years ago—I certainly try never to take any shots at my predecessors, and Nancy-Ann Min Deparle is a good friend of mine. She had other things to focus on, including a lot of legislative mandates in 1997 and Y2K. I came in at a quieter time legislatively. I have been able to focus more of my efforts on trying to change some of the things at the Health Care Financing Administration (HCFA) and turn it into a warmer, friendlier, more responsive agency.

The first step was to change the name, which some people thought was not necessary, but I think it has worked out very well. I think it has changed the attitude of the employees and of the people who work in the agency. Sometimes as I somewhat jokingly say, my guess is when Enron comes out of bankruptcy, I think they will have a new name.

I think we had a similar perception problem in HCFA. The new name has helped change the attitude. It is a huge, complex agency,

administering a huge, complex program. We are never going to completely tame the monster, but I think we have done a good job at trying to get started.

One of the things that I initiated 2 years ago which I think has helped—we created 12 what we call open-door policy groups. We have had meetings at least once each month with each one. I Chair three of them. One of the senior people at CMS Chairs each one. There is one for minority involvement, there is one addressing the disabled, for hospitals, doctors, nursing homes; virtually every group we deal with.

I hope it has provided—we will hear from providers and beneficiary groups—provided a much greater access to the agency. It has also created, I believe, the correct approach from the staff, that it is okay to talk to them on the outside, explain what you are doing, and justify the policies.

I don't expect everybody to like our policies. I expect them to be fair, thoroughly explained, thoroughly vetted. If we are doing the right thing, I am happy to back up the staff and defend them. We have had 135 of those open-door policy meetings in the last year and a half. We have had 14,000 people in the health care community involved in those meetings. I think they have been very successful.

I also think we probably were not particularly popular with Congress. I have attended 47 open-door town hall meetings with Members of Congress on both sides of the aisle in the last year and a half. I think going out and talking to your own providers in the community and trying to give them the impression that CMS is open and available to talk to them, we are trying to be a lot more responsive, has helped. It has helped change the perception of the Agency.

Also, one of the major concerns, fair or unfair, we have heard in the last couple of years is about enforcement, unfairly picking on doctors and providers. I think we are every bit as fair as we have been in the past, but I also think we have changed our approach to be less aggressive and more reasonable with people who are first-time offenders and don't have a long track record.

We have adopted some new standards. We will get into those in a second. I hope you will find from the provider community—we should be extremely aggressive with bad providers. There are some out there. I think we should also be reasonable with providers who made marginal mistakes that don't have a long track record.

In addressing this whole issue when Secretary Thompson came in 2 years ago, he created the secretary's Advisory Committee on Regulatory Reform, which has been chaired by Dr. Wood. We have spent a lot of time with Dr. Wood. He is not only Chair of the Committee, he is also on the Practicing Physician Advisory Council, which is CMS's Physician's Advisory Committee. I am not sure if he ever gets back to Minnesota, since I see more of him than his family does. He has been extremely involved and unbelievably helpful to the Secretary and me in the last year and a half as we try to address these issues.

Madam Chairman and Congressman Stark, there are a whole variety of what I call HCFA frustration bills over the last couple of years to deal with problems that were perceived and real at CMS/

HCFA to try to change the way we do business. There are huge issues, I will try to go through some in my allotted time, that are very big.

The first one is transferring the Administrative Law Judge (ALJ) function from Social Security to CMS, to the U.S. Department of Health and Human Services (HHS). Many people don't realize that since the beginning of the program, Social Security has heard our appeals—provider appeals. If you are a beneficiary—excuse me—and you have a concern about your bills being paid, you don't go to HHS, you go to Social Security. It hears 90,000 appeals a year. We process about 1 billion Medicare claims a year. Social Security has a backlog of about 440 days to complete a case. Obviously, that is unacceptable.

As you know, you and Chairman Thomas and many others pushed through some pretty significant reforms in sections 521 and 522 of the Beneficiary Improvement Protection Act (BIPA) 2 years ago. Secretary Thomas has been pretty angry with me, as you know, that we have not carried it out yet. We are anxious to do that. We think we need to significantly reform the process. We were frustrated Congress did not appropriate money to do it the last couple of years. I spent a lot of time trying to get the appropriators to get started this last year and we did not get any.

We got $129 million in the 2004 budget that just came out. It is not as much as we think is necessary to do the job, but we do think we get some modest changes to sections 521 and 522 to get some changes. We can go forward with fixing the provider appeals process and the beneficiary appeals process to make them smoother, faster, fairer, and more efficient. It is going to take a lot of work.

Our current budget assumes we are going to do this on October 1 of this year. I think it is going to be very difficult. I have spent a lot of time talking to Jo Anne Barnhart, the Social Security Administrator. I think, with Social Security's help and cooperation, we can get started in moving forward on that. I can tell you that we are committed to doing that because I think both providers and beneficiaries have been extremely frustrated, with some justification, about the slowness and inefficiency of the Medicare appeals process.

We have made, as you know, Madam Chairman, a number of suggestions for modest changes that we think will in fact improve sections 521 and 522 and make it easier and faster for us to carry out and basically meet the spirit and targets of what you were trying to do when you tried to—when you very rationally tried to reform those programs.

Just to run through a couple of other regulatory issues that we have also taken on that Dr. Wood has looked at, in most of the bills in the House you have required us to consolidate promulgation of rules to once a month. We are already doing that in the vast majority of cases. We did that starting last year. We put out a compendium on the fourth Friday of every month of all the rules to come out. We put out a quarterly provider update that basically gives a heads-up as to what regulations are coming during the quarter, ahead of time, so people can follow them.

The goal here, which I think we've met, is to not require every hospital and physician group and provider in the country to have

to hire a lawyer to comb through the Federal Register to follow these rules. It is an incredibly time-consuming process. I used to get paid a lot to do that myself when I was a lawyer. It is a very time-consuming process. I hope the provider groups will tell you that we have significantly simplified that and made it much easier.

We have also come up with a much more simple way of tracking our error rates, which is the Comprehensive Error Rate Testing Program. That is also in many of the bills. Also, most of the bills require prompt responses to Medicare contractors. We are already doing that as of now within 45 business days, which most of the bills have, to respond to contractor inquiries. Random prepayment review—most of the bills in the House and Senate has prohibited this. We have already adopted a policy where we only use random prepayment reviews where there is a contractor-wide program for doing so, which most of the bills require.

Non-random prepayment review, which most bills also suggest should not be done in the future, has been limited under our new policy to where we can show a very aggressive track record of particular billing and a high level of payment problems.

I could go on for others, but the bottom line is, most of the provisions in the bill that I think were listed in most of the CMS/HCFA reform bills in the last 2 years I think we have addressed pretty aggressively. We are getting there as quickly as we can.

On contracting reform, a big, big issue for us—and I know I am already over my 5 minutes but I will do this quickly. When I went to the Office of Management and Budget (OMB) in 1989 we had over 100 fiscal intermediaries (FI) and carriers. Our goal was to get it down to 10. When I came back 10 years later, we still had 51. In the last year and a half we have gotten the number of carriers and FIs, down to 46. We really think to manage the program—the hospital, still, theoretically picks their hospital intermediaries, we are allowed to pick the carriers—but generally we still have mostly local BlueCross plans that do a great job around the country, but we have 71 percent of the work, both in Part A and B, done by the eight biggest contractors.

We believe we could move more work to contractors who are in this in the long haul, incentivize them, and they can be partners of the government in the long haul. We can manage the resources better and be more efficient. We already, as I mentioned, have the bulk of the work done by eight contractors in both parts of the program. We believe contractor reform will allow us to manage the program more effectively and efficiently.

As I mentioned, theoretically in Part A, BlueCross is the contracting entity. While that has worked well over the years, we think we should have the flexibility to hire other non-Blue contractors and to contract directly. Now there are only two non-BlueCross contractors or fiscal intermediaries: EDS heritage, and mutual of Omaha. We believe there might be many other people that might have the technology and expertise in paying claims that can help us.

Many of the BlueCross plans have done a terrific job, they are committed to being good partners in the long run, but in the modern era where there are many people that can pay health care

claims we should have a competitive system to have the best contractors to be our partners in the long run.

To wrap up, Madam Chairman, I will say we spent $540 billion as our budget this year for Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). We run that on a $2.5 billion administrative budget, which about $1.5-$1.6 billion goes to the contractors. It is a very big program to run. Trying to do it while we minimize fraud and only have the minimum amount of harassment necessary to providers and be more open and effective is obviously our goal.

It is a big program. We spend a lot of taxpayer money. We need to be aggressive in enforcing those regulations, and we will be. Secretary Thompson and I also believe that, in tandem with being aggressive on the regulatory side, we need to push out much more quality information.

As you know, we have been very aggressive with work in the nursing homes on quality information. We have a new program coming out with home health agencies that is similar to the nursing home quality measures in about 2 weeks. We have worked very well with the hospitals so far in doing voluntary hospital measurements. Our goal is to move forward with the hospitals to have really good quality measurements. We can start really measuring what every hospital provides quality-wise.

We believe in addition to aggressive regulation, giving patients and consumers more information to make their choices is every bit as important a regulatory tool as putting out hundreds of thousands of pages of regulations.

We also believe it is a very important regulatory tool to work with the Federal Trade Commission (FTC) on antitrust enforcement. If you really want physicians and hospitals and health care plans to have the right balance in every local market to make sure the market does not get out of whack with any of the major provider sectors, they need to be working with the FTC. The FTC needs to work with many of our big programs to make sure there is a rational balance in each local market between hospitals, physicians, and managed care plans. In a well-functioning market, they should all be working with each other almost every day. That is the way we believe it should work.

We believe it is our duty, also, and we are working very closely with the FTC to make sure that the antitrust laws are aggressively enforced in health care. That is as important to us as the regulatory roles.

That is as fast as I can talk, Madam Chairman. Thank you very much.

[The prepared statement of Mr. Scully follows:]

Statement of the Honorable Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services

Chairman Johnson, Congressman Stark, distinguished Subcommittee members, thank you for inviting me to discuss Medicare regulatory and contracting reform. We all want to improve our ability to serve our nation's elderly and disabled, and I want to thank you for your continued interest in increasing the efficiency and quality of the Medicare program. Over the past two years, I have appreciated your support of our efforts to eliminate unnecessary regulatory burdens and improve contractor oversight at the Centers for Medicare & Medicaid Services (CMS). I applaud

your commitment to these important issues. Building on these efforts, there is now a clear opportunity to improve Medicare even further in this legislative session.

As you know, strengthening and improving the Medicare program remains one of the Administration's top priorities. Additionally, the Administration remains committed to updating and streamlining Medicare's regulations and administrative procedures to reduce the time devoted to paperwork and encourage high-quality health care for all seniors. The Secretary's Advisory Committee on Regulatory Reform, which my fellow witness today, Dr. Wood, chaired and for which he traveled all over the country, heard from patients and providers about the Department's regulations and opportunities to improve them. I would like to personally thank Dr. Wood for his hours of work chairing the Committee, as well as his service on the Practicing Physicians Advisory Council (PPAC). Even before this report was complete, we had begun working on many of the changes the Committee recommended. These recommendations, along with a host of other efforts within CMS and the Department, have led to great strides in making CMS a better business partner and in making Medicare a more efficient program. We are reviewing all of the Committee's recommendations to identify those that can be implemented quickly, and those that will require more significant development and resources.

In some cases, reform requires legislation. H.R. 3391, the Medicare Regulatory and Contracting Reform Act, includes reforms that are vital to streamlining Medicare's administrative processes and reducing regulatory burden. While we do have some concerns with this legislation, most of them are largely technical in nature and we look forward to working with you and your staff to resolve them quickly.

SECRETARY'S ADVISORY COMMITTEE ON REGULATORY REFORM

First, I want to take this opportunity to convey my gratitude for Dr. Wood and the members of the Secretary's Advisory Committee on Regulatory Reform that developed more than 250 specific recommendations, a majority of which pertain to CMS. President Bush, Secretary Thompson, Assistant Secretary for Planning and Evaluation Bobby Jindal and I share the view that, in an effort to protect public health and safety, federal regulations must be crafted to ensure access to high quality health care. The Secretary asked Bobby Jindal to lead the initiative and established a steering committee on which other HHS officials and I participated to provide guidance and direction to an ongoing review of HHS regulations. We are addressing a significant portion of the Committee's report by reducing the burden of inefficient, as well as unnecessarily complex and confusing regulations. As you know, we have already implemented recommendations made by the Committee that will reduce the burden of data collection on beneficiaries and providers. These are common-sense solutions to ensure that health care professionals can spend more time with patients and less time with paperwork. For example:

- Medicare reduced the frequency that hospitals must gather detailed information from Medicare beneficiaries about other insurance. Hospitals will now be able to gather this Medicare Secondary Payer information—used to make sure the correct insurer pays each health care claim—once every 90 days. This change means hospitals will not have to ask patients repeatedly for the same data.
- We have launched a new effort to streamline Medicare's paperwork requirements for home health nurses and therapists so that they can focus more on providing quality care to their patients. The Outcomes and Assessment Information Set (OASIS) requirements were reduced by approximately 27 percent, and these changes will streamline Medicare's home health patient assessment requirements to include only those elements needed to promote quality of care and to ensure proper payment.
- Medicare has streamlined its paperwork requirements for nurses and other clinical staff caring for Medicare beneficiaries in nursing homes. While certain longer assessments are still required, nursing homes caring for Medicare beneficiaries can now use a shorter assessment form to gather information needed to pay Medicare claims. The change cuts the time it takes to complete the assessment form from 90 minutes to 45 minutes, while continuing to collect data needed to measure quality of care in nursing homes.

I also want to mention, in addition to the Secretary's Advisory Committee, we have been inviting nursing homes, home health agencies, physicians, hospitals, other providers, and beneficiaries to participate in "Open Door Forums" to discuss their ideas for simplifying Medicare regulations. We have had 135 of these meetings, with more than two thousand in-person participants and over eleven thousand participants on our toll-free call-in lines. We have been able to make many improvements based on their concerns, as well as based on other activities that we are pur-

suing. Most importantly, it has helped change the image of CMS as an "impenetrable bureaucracy."

LEGISLATIVE OPPORTUNITIES FOR REGULATORY AND CONTRACTING REFORM

Clearly, we have worked diligently toward eliminating unnecessary regulatory burdens in Medicare and improving our management of the private-sector contractors that process and pay Medicare claims. We need to make the Medicare contracting system more consistent with standard federal government contracting procedures, which are typically governed by the Federal Acquisition Regulation (FAR). The President's FY2004 budget includes provisions to implement Medicare appeals reform, to continue pursuing contracting reform, to address provider education, and for program integrity efforts to ensure that the Medicare program pays appropriately for covered services. We remain committed to these activities—they are integral to strengthening and improving the Medicare program so we can better serve America's seniors and disabled citizens.

While H.R. 3391 addresses many important issues that respond to the concerns of our partners, in a number of these areas, we believe that some of the proposed legislative changes have been overtaken by our current administrative practices, and could prove duplicative or counterproductive. In addition, codifying these areas could prevent CMS from administratively making further improvements in the future—by reducing management flexibilities and constraining our ability to manage taxpayer dollars as efficiently as possible.

Appeals

One area where we have concerns with the legislation is in Medicare appeals. As required by law, we provide a multi-level process for Medicare beneficiaries, providers, and suppliers to appeal when they disagree with a Medicare contractor's decision to deny Medicare claims for items or services. We recognize the need to make this process more efficient and accurate. As I speak, we are working aggressively to implement the Medicare appeals reform as required by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). The President's budget includes a request for funding to cover implementation costs. We are proceeding toward the transfer to CMS of the Medicare hearing function currently performed by the Administrative Law Judges (ALJ) in the Social Security Administration (SSA). We have already had extensive discussions with SSA to explore administratively transferring the Medicare hearing function to CMS.

There are several technical areas that we consider priorities in making the BIPA appeals provisions more efficient. We are moving forward and have published Notices of Proposed Rulemaking on both sections 521 and 522. However, we are concerned that the current BIPA section 521 timeframes for decision-making at each level of the appeals process are not viable. Extending these timeframes for review at each appellate level would create a more workable timetable and would reduce the number of cases that proceed to higher and more costly levels of adjudication. Specifically, I would recommend that the timeframes at the contractor level should remain at 45 days for Medicare Part B reviews and 90 days for Medicare Part A reconsiderations. In addition, the timeframes might be extended to 60 days at the qualified independent contractor (QIC) level and to 180 days at both the ALJ and Departmental Appeals Board levels. Finally, we have asked for consideration of legislation that would reduce the current number of QICs from 12 to "not fewer than 4." This number would do the job, but be far more efficient and faster to implement. If needed, the Secretary could add more QICs in the future.

We truly need to implement sections 521 and 522 and, with your support, we expect to make great headway this year.

Regulations

In addition to improving the appeals process, we are committed to reducing regulatory burden on providers so that they can spend more time taking care of patients and less time filling out unnecessary paperwork. As I mentioned, we have already undertaken numerous actions to reduce burden and streamline administrative processes. For instance, in October 2001, we began publishing regulations on the fourth Friday of every month (except in cases where a statutory deadline or extenuating circumstances demand otherwise), and we began issuing a quarterly publication that I am extremely proud of, called the *Quarterly Provider Update*. It lists all the regulations that CMS plans to publish in the coming quarter, as well as the publication date and page reference to all regulations published in the previous quarter. The *Quarterly Provider Update* is available on the CMS website with links to the complete text of published regulations. One year later, on October 1, 2002, we implemented a "subscriber service" that allows the public to receive automatic updates

to the *Quarterly Provider Update*. Less than five months later, we have nearly five thousand subscribers, and that number grows daily. Now, instead of providers hiring regulatory experts to comb through thousands of pages of the *Federal Register* every day, they can simply subscribe and receive updates as they occur.

We are committed to both of these endeavors—they are integral to providing our partners the information they need to serve seniors and disabled citizens. Of course, some regulations have statutorily imposed publication dates or other extenuating circumstances that do not lend themselves to a one-day-a-month publication schedule, but the bulk of our activities have been simplified. We believe this flexibility is critical. In addition, we also are including in the *Quarterly Provider Update* all program memoranda, manual changes, and any other instruction that could affect providers in any way. All of these instructions are included one quarter prior to their effective date to allow providers time to react before new requirements are placed on them. Since we have already taken administrative steps to streamline this part of the regulatory process and be more accountable to beneficiaries, providers, and the public, such provisions do not need to be included in legislation.

Provider Education

Another integral part of our regulatory reform efforts is our work to improve performance through provider education and outreach. We have expanded our Local Provider Education and Training program (LPET). This year we doubled funding for LPET, which is targeted to respond to problems identified through the review of claims. Providers are receiving more education related to their claims submission. Clinicians deliver most of the education, and respond to specific coverage or coding issues. Contractors meet with providers in group settings, individually, or communicate using the Internet. As a result, our contacts with the provider community are more collaborative and productive.

In another step to address provider education, H.R. 3391 would require contractors to provide general written responses to specific provider and supplier billing and cost reporting questions within 45 business days of receipt of inquiries. I take some pride in reporting to you that since May 2000, CMS contractors have been required to do this, and so it need not be included in legislation.

Comprehensive Error Rate Testing

H.R. 3391 would also require the Secretary to develop a methodology to assess the specific claims payment error rate of contractors. However, we currently have a practice in place to assess specific claims payment error rates of contractors, and to codify a procedure might limit our flexibility to make further improvements in the future. We developed the Comprehensive Error Rate Testing (CERT) program to improve the processing and medical decision making involved with payment of Medicare claims. The CERT program, which began in August 2000, will produce national, contractor, provider-type and benefit category specific paid claims error rates. Unlike the former improper payment calculation, the CERT program will allow CMS to estimate specific error rates for individual contractors, providers and benefits. The new information will continue to be aggregated to produce national level estimates like those calculated by the Office of the Inspector General (OIG), but with much greater precision, because so many more claims will be reviewed. The CERT system will examine 24 times more claims than the current process has been able to review. This will give us greater ability to see how well the Medicare contractors are performing and allow us to pinpoint problems, fix them, and ensure that our rules are being followed. Our intention has been and will continue to be that the Medicare Trust Funds benefit from improved claims accuracy and payment processes.

Review, Recovery and Enforcement

Regarding review, recovery and enforcement, I am also happy to report that in many of the instances to follow, we are already performing to the intent of your legislative provisions.

For example, H.R. 3391 would prohibit random prepayment review, except to develop a contractor-wide or program-wide claims payment error rate, or under additional circumstances that may be provided under regulation. Currently, we only use random prepayment review to develop contractor-wide or program-wide claims payment error rates. However, this important tool may offer other benefits to the Medicare program in the future and we believe that the flexibility to determine the appropriate use of random review is integral to managing our programs effectively.

Also included in H.R. 3391, is a provision stating that contractors may not initiate non-random prepayment review of a provider based on the initial identification by that provider of an improper billing practice—unless there is a likelihood of sustained or high level of payment error. Currently, the only time CMS contractors ini-

tiate non-random prepayment review is when there is a high level of payment error or the documented educational interventions have failed to correct the problem. Our contractors perform the medical review through a process called *Progressive Corrective Action*. In this process, contractors perform data analysis to determine whether patterns of provider claims submission and payment indicate potential problems. If through data analysis a potential problem is detected, a contractor may perform a "probe" sample. Only when the probe review reveals that there is a major error will a contractor perform high level prepayment review.

In fact, in a recent study, the General Accounting Office examined three Medicare carriers and determined that the *Progressive Corrective Action* policy has reduced medical reviews of claims and has increased carrier education to individual physicians. According to the report, 90 percent of physician practices had no claims selected for complex medical review by carriers. For the few practices that were reviewed, typically the carriers requested documentation to support no more than two claims for the year.

Additionally, under our *Progressive Corrective Action* policy, we currently perform several activities that are included in provisions in H.R. 3391. First, when a contractor audits a provider or supplier, under H.R. 3391, the contractor would be required to:

- Give the provider and supplier an opportunity to provide additional information and take into account information provided on a timely basis;
- Give the provider or supplier a full review and explanation of the findings of the audit; and
- Inform the provider or supplier of their appeal rights.

Second, H.R. 3391 would require the Secretary to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern. Both activities are current practice under our *Progressive Corrective Action* policy, and do not need to be included in legislation.

Contracting Reform

As you know, the Administration's primary goals for Medicare contracting reform include providing CMS with more flexibility to adapt its business model to meet the evolving needs of the Medicare program and bringing competitive discipline to the world of Medicare administrative contracting. We also believe that contracting reform will provide opportunities to improve communication between CMS, contractors and providers, and will promote our ability to reward contractors that perform in an excellent manner. I want to thank this Committee for its sustained interest in and support for Medicare contracting reform.

We have been working to consolidate contractor functions for some time. When I went to OMB in 1989, we had well more than 100 fiscal intermediary and carrier contracts and our target was to get that to ten. Thirteen years later, I came to CMS and there were still more than 50 separate intermediary and carrier contracts. Over the past decade, we have seen a substantial consolidation in the number of these contractors, so that, at present, we are at 46 and counting: Medicare claims are processed by 27 fiscal intermediaries (4 of which also specialize in the handling of home health and hospice bills) and 19 carriers (4 of which specialize in the handling of DME claims). My goal is to find the best contractors, incentivize them appropriately, and work with about 20 to 25 who are in it for the long haul.

While H.R. 3391 certainly addresses many important contracting reform issues, I have several additional suggestions I would like to present to you regarding certain policy and technical details. We would be pleased to work with you and your staff on these issues.

For example, the legislation prescribes definite time periods for re-competition of Medicare administrative contracts—every 5 years, provided that the contractor has met or exceeded all applicable performance requirements. We are concerned that these contract period limitations may be too short in some circumstances.

Currently, Medicare contractors are reimbursed for their claims processing and benefit administration activities on a cost-reimbursement basis, which leaves little financial incentive for the contractors to excel in their performance. This is not realistic in today's business environment, given the magnitude of these contracts. The contracting reform legislation would provide us with the ability to address this issue on a broad scale.

Moreover, we are moving forward to test the effectiveness of performance-based payment mechanisms for Medicare contractors on a pilot basis under current law. For fiscal year 2003, for example, we are using a demonstration authority to conduct performance-based contracting pilots with three significant Medicare contractors:

CIGNA, UGS and Palmetto. If these efforts prove successful in defining outcomes and achieving some efficiencies, the demonstration could be expanded to include additional Medicare contractors. In addition, we have effectively implemented contracting reform as part of the Medicare Integrity Program. All Program Safeguard Contractors are under performance-based contracts containing award fee plans. These endeavors will give the Agency valuable experience in applying new contracting tools that will become broadly available under HR. 3391.

CONCLUSION

From my experiences in the hospital sector and in health care generally, I know how important it is that Medicare work more efficiently, and that its regulations be less burdensome. Time and again, this Administration has confirmed its commitment to regulatory and contracting reform. I want to thank you for your unflagging efforts to pursuing these reforms and for your interest in increasing the efficiency of the Medicare program. Improvements in our efficiency result in improvements and speed in paying providers for treating their patients, our Medicare beneficiaries. We have already made great strides in this area, and we strongly encourage your legislative efforts to that end while allowing us to retain the flexibility to continue improving administratively. We look forward to working with you, Chairman Johnson, Mr. Stark and this Subcommittee, to enact needed reforms as soon as possible. We owe it to Medicare beneficiaries and all of Medicare's partners—providers, contractors, and others, to achieve these reforms. Thank you for the opportunity to discuss this important topic with you today. I look forward to answering your questions.

Chairman JOHNSON. For you, that is some statement. Thanks very much. Dr. Wood.

STATEMENT OF DOUGLAS L. WOOD, M.D., VICE CHAIR, DEPARTMENT OF MEDICINE, MAYO CLINIC AND FOUNDATION, ROCHESTER, MINNESOTA

Dr. WOOD. I will see if I can go as fast.

Chairman Johnson, Congressman Stark, and other distinguished Members of the Subcommittee, I am privileged to have this opportunity to share with you my insights about regulatory reform.

I am a practicing cardiologist and Vice-Chair of the Department of Medicine at the Mayo Clinic. It was my honor to serve Secretary Thompson as Chair of his Advisory Committee on Regulatory Reform.

I appreciate your interest in our work. I hope in the very short time that I have with you today I can leave you with a better understanding of how we did our work and what we tried to do. I hope it will be helpful for you in thinking about legislative proposals that you might continue to undertake in a way that would improve the Medicare program for its beneficiaries as well as for those providers who care for our older Americans. The statement that I provided has additional detailed information.

Our group represented all sectors of health care, including consumers. We did not organize along industry lines as we conducted our work but, rather, we tried to take the perspective of consumers and beneficiaries as they encountered the Medicare program and the health care system.

We worked hard to be able to accomplish the large task to evaluate Medicare and Medicaid and the Food and Drug Administration (FDA) for opportunities to improve the regulatory burden. In that, we visited hospital emergency rooms, we went to inner-city clinics, we went to rural clinics where nurse practitioners were trying their

hardest to care for patients in the face of what they considered to be stifling and suffocating regulatory limitations.

We carefully studied the original intent of law and regulation. We heard testimony from providers and the public about how regulations worked in everyday application. Everyplace we went, we took time to listen to people. We had open-comment sessions where anyone from the public could come and share with us their particular insights.

We learned that the regulations in the program have become so complex that beneficiaries now are being denied services that they should be receiving. In some circumstances, the regulations are so difficult that rural health care providers decided not to avail themselves of resources that are available to them because the regulations that govern the programs make it so complicated to apply that it is almost equivalent to applying for a research budget in the National Institutes of Health.

We approached our work with a clear vision of direction and set of principles for selection of issues and actions. We concentrated on those areas that we thought would have the most adverse effect on the patient/provider relationship, which indeed is the most important aspect of health care.

We were asked by the Secretary to identify potential solutions to regulatory problems as quickly as possible, and we worked hard at that. The Secretary and Mr. Scully announced recommendations of their own to address some of the suggestions that we had made at our meetings, including some improvements to the Medicare card that gave Medicare beneficiaries an easy number to follow to call for help, and a Web site that they could then also access for help.

I am pleased to say that both the Secretary and Mr. Scully have remained actively engaged in the evaluation of our remaining recommendations and the execution of improvements in those regulations.

During our work we studied areas of concern by developing panel discussions for an in-depth analysis of issues, and those panels have been summarized on page 7 of my written statement to give you a sense of some of the major areas that we discussed. Those were derived from the perspective of listening to beneficiaries as well as listening to people in the field.

The recommendations that were made, as noted by Mr. Scully, number 255 specific recommendations. There were also a series of long-term recommendations. Some of the themes of these adopted recommendations, along with a number of recommendations in each theme area, can be found on page 8 of the written testimony.

Now, I would call your attention to the fact that more than 50 of these recommendations are actually aimed at specifically helping beneficiaries. There are more than 80 of them that in some way or another refer to improvement of communication in the Medicare program. In its work already, HHS has accomplished about 30 of these recommendations and has started work on some of the others. I know that the Secretary has commissioned a new strike force in HHS to continue the implementation.

Now, there are some other things that could be done. If you look in appendix C, Unfinished Business, you will find some opportunities to help us make the program work better, with some legislative

support; in particular, finding ways that we can integrate data across programs to eliminate the barriers and the silos that provide barriers not only to access but to the ability to provide quality information that helps consumers make the best choices about their health care.

My group actually failed the mother-in-law test. My mother-in law, when she heard about my activity, said, I want you to fix one thing. Can you please find a way that I can get the same thing paid for in Missouri that I get in Minnesota, or vice versa? Her biggest concern is that when she comes to Mayo, she can't get certain things paid for that she can get paid for in Missouri. She couldn't quite understand that. That is the advanced beneficiary notice problem and need for prior coverage determination in Medicare. We are pleased there are some provisions that are in legislation that will in fact address that.

There are some other opportunities. They will be highlighted by other folks today as they provide their testimony. We are certainly interested in doing all we can to help you understand where those opportunities might be.

Again, thank you for the opportunity to come today. Obviously, the Secretary's Advisory Committee is interested in all of the support that you and your colleagues have in helping to improve the Medicare program for its beneficiaries across the country. Thank you.

Chairman JOHNSON. Thank you very much.

[The prepared statement of Dr. Wood follows:]

Statement of Douglas L. Wood, M.D., Vice Chair, Department of Medicine, Mayo Clinic and Foundation, Rochester, Minnesota

Chairwoman Johnson, Mister Stark and members of the Subcommittee, I am privileged to have this opportunity to share with you my insights about regulatory reform. I am a practicing cardiologist and Vice-Chair of the Department of Medicine at the Mayo Clinic in Rochester, Minnesota. I was honored to serve Secretary Thompson as Chair of the Secretary's Advisory Committee on Regulatory Reform. I appreciate your interest in our work and hope that in my short time with you today I can leave you with a better understanding of our work and recommendations. I especially hope that the information I have for you will be helpful in your work to improve the Medicare program for its beneficiaries and the providers who care for older Americans. This written statement provides more detailed supplemental information for my oral comments.

Schedule of Work

The Secretary's Advisory Committee was chartered by Secretary Thompson in August 2001, but its start was delayed by the terrorist attacks on this great nation and the subsequent anthrax exposures here in Washington. We began our work in earnest in January, 2002 and provided a final report [1] to Secretary Thompson by November of 2002. Our report included more than 250 specific recommendations to the Secretary as well as some thoughts about long term changes in the way that HHS conducts its business.

Work Process

Our group represented all sectors of health care, including consumers. We worked in subcommittees to be able to accomplish the large task we were given, specifically to evaluate Medicare, Medicaid and the FDA for opportunities to reduce regulatory burden in health care and improve regulatory processes in the Department of Health and Human Services. We solicited written comments, electronic comments on our web site,[2] and we conducted listening sessions with CMS and FDA staff as

[1] Bringing Common Sense to Health Care Regulation, Report of the Secretary's Advisory Commit on Regulatory Reform, 2002.

[2] http://regreform.hhs.gov.

well as beneficiary advocates and contractor executives. We visited different parts of the country to understand the impact of regulations on the process of care. In our work, we visited urban hospital emergency rooms and inner city clinics, we went to rural hospitals and clinics, we went to nursing homes and we went on home health nurse visits. We carefully studied the original intent of law and regulation and we heard testimony from providers and the public about how regulations worked in everyday application. At every meeting, there were multiple sessions for public comment where any interested person could come and share comments with us.

Regulatory Complexity Is a Barrier to Beneficiaries

We learned that the regulations in the Medicare program have become so complex that beneficiaries have been denied services they were entitled to receive. We learned of contractor medical director decisions that persons near death and entitled to hospice benefits could not receive them as intended. We learned that providers and patients in rural areas did not take advantage of programs intended to help them because the procedures to apply for resources and to sustain them required nearly the amount of work to apply for a NIH sponsored research award.

Committee Mission

We approached our work with a clear vision of our direction and principles for selection of issues for action.

Mission
To improve the level of services for patients and consumers. We will do this by:

(1) cutting red tape,
(2) removing obstacles to smoothly functioning relationships in the health care system, and
(3) reducing burden appropriately so time and resources currently devoted to program requirements can be redirected towards patient care.

We recognize the need to enhance the trust of Americans that they will be well-cared for, served, and protected.

We concentrated on those areas that appeared to have the most adverse effect on the patient-provider relationship, the most important aspect of health care.

Principles for Issue Identification

Early in the planning for the committee work, it was apparent that we would have limited time and many opportunities. It would be important to prioritize our efforts if we were ultimately going to be successful in our work. Thus, at our first meeting, we discussed and adopted principles for identification of issues that the Committee would address. These principles were:

- Develop recommendations about issues that have the most significant and direct effect on improving care and service to patients and consumers
- Select issues for deliberation on which meaningful progress can be made during the year, but that may not be entirely resolved, in addition to identifying and "fixing" several concrete problems. The Committee will identify a mix of immediate fixes (what can be done now), short-term fixes (what can be done in 6 to 12 months), and long-term fixes (beyond one year).
- Attempt to identify problems that are likely to persist even in a period of program stability. For example, much of the burden in the past few years has stemmed from the extraordinary pace at which Congress has been modifying the Medicare program, along with confusion and delays in implementing the changes.
- Concentrate on existing programs and focus on solutions to remove impediments to realizing current goals

What We Did Not Do

- Pursue new policy goals (i.e., find new places to regulate).
- Prioritize or make recommendations on issues that are anecdotal or relevant only to specific special interests. Assess the adequacy of payment levels or the fairness or accuracy of payment methodologies
- Engage in "what-if" scenarios about program function (e.g., effect of changes in fee-for-service, Medicare + Choice or provider participation rates)

We were asked by Secretary Thompson to identify potential solutions to regulatory problems as soon as possible and not to wait for the preparation of a final report to make recommendations for solutions to regulatory problems. HHS staff

members were actively engaged in our work, attending every meeting, listening to all the testimony and to the thoughts and recommendations of the Committee. Indeed, the staff members began work on several of our recommendations as soon as they were identified and had completed some of these tasks even before we prepared our final report. Secretary Thompson and Administrator Scully announced solutions to some of these problems at our meetings, including improvements to the Medicare card to make it easier for beneficiaries to find contact phone numbers for information. Secretary Thompson and Mr. Scully remain actively engaged in the evaluation of our remaining recommendations and execution of improvements in regulation.

SACRR Panels

During our work, we studied areas of concern in detail by developing panel discussions for in-depth study of significant issues. In this approach, we asked HHS staff with responsibility for a specific area to provide the Committee with a summary of the legislative and regulatory history of an area of regulation. We then invited people with specific expertise and experience in each of the areas to share their real world experience with the impact of regulation on their work with beneficiaries. Wherever possible, we also sought to identify best practices among CMS regional offices, Medicare-Medicaid coordination activities and FDA and CMS activities that we could use as a basis for recommendations for future improvements. The Panels were developed to address major concerns identified in public comment and early deliberations of the Committee. The panels explored the following areas:

- EMTALA
- OASIS and Home Health
- MDS and Nursing Homes
- Beneficiary Communications/Limited English Proficiency
- Beneficiary Education
- FDA
- FDA-CMS Interaction
- Dual Eligibles
- Rural Health Care
- Multiple Reviews
- HIPAA Privacy
- HIPAA Transactions/Security
- Administrative Simplification
- Medicare + Choice
- Provider-Patient Relationships
- Federal-State Coordination
- Adverse Events
- Provider Enrollment/Forms
- Advanced Beneficiary Notices
- CLIA

After each panel discussion, the Committee identified specific areas for evaluation, and assigned these to subcommittees for more detailed analysis and recommendations. The subcommittees then presented the Committee with issue statements that could be evaluated by HHS staff to better understand the potential implications of possible recommendations.

Recommendations of the Committee

The Secretary's Advisory Committee on Regulatory Reform adopted 255 specific recommendations. Some themes of adopted recommendations (along with the number of recommendations in that area in parentheses) are listed below.

EMTALA	13
Beneficiary Education & Communications	33
OASIS	14
MDS	22
Medicare + Choice	15
HIPAA Privacy	17
Rural Health	10
Multiple Reviews/Audits	65
HIPAA Transactions	8
Federal-State Coordination	19
Adverse Events	6
Contractor Relations	29
Provider Enrollment/Forms	11
ABNs	7
CLIA	12
Cost Reports	5

HHS has already accomplished 30 of the recommendations and has started initial work on about half the rest. The Secretary has commissioned a new strike force in HHS to continue implementation of the Committee's recommendations.

Long Term Recommendations

The Committee also made several recommendations for the Secretary to improve the regulatory function at HHS to achieve better service to beneficiaries, improved coordination between groups within HHS and better communication with the industry.

While health care innovation has progressed rapidly, rules that govern federal health care programs have not kept pace. We encouraged the adoption of technology to improve access to care, streamline enrollment processes for beneficiaries and providers, better serve beneficiaries and providers with information about benefits and claim status, streamline program operation, and most important, improve the quality of care for beneficiaries. The savings that would accrue from streamlining program function and improving quality of care could be reinvested in extending benefits or reducing costs to beneficiaries and taxpayers.

Areas Requiring Legislative Solutions

During the course of our work, we encountered problems that could not be solved on a regulatory level, but instead would require a legislative solution. These are identified with asterisks in Appendix B of our report, but I will highlight some of them for you. I have also prepared an analysis that shows a relationship between our recommendations and provisions of House resolutions.

One of the most vexing problems faced by Medicare beneficiaries is their inability to determine whether a physician's service, or a laboratory or x-ray test, or a specific procedure or technology is covered by Medicare. This is an excessively complicated process for patients and providers alike, and it was our recommendation that Medicare should provide an advance coverage determination for its beneficiaries. This will require legislative authority and your resolution is consistent with the Committee's recommendations.

For the long term, the Secretary's Advisory Committee suggested:

- the creation of a public-private partnership to establish quality standards that would strengthen the safety of services and reduce unnecessary or duplicative services
- a new emphasis on changes in the statutory basis for reimbursement within existing expenditure constraints that would reward quality outcomes, recognize the need to balance acute care services with the growing need for services provided to the chronically ill and those requiring long-term care
- a more global system of payment within governmental program that gives patients more choice and greater ability to be prudent users of public resources
- integration of information systems to be patient or beneficiary oriented rather than program oriented.

Conclusion

The Secretary's Advisory Committee on Regulatory Reform provided 255 recommendations for easing the burden of regulation and improving service to Medicare beneficiaries and others. And, we made specific suggestions for future operations within HHS. The Committee members recognized that effective delivery of health care resources requires a balance of regulation, financing and a societal expectation. While our group effectively addressed the regulatory aspects of this complex relationship, we did not address financing nor did we carefully study or try to articulate a societal expectation. For this, we are grateful for the leadership of the members of this subcommittee. We appreciate your interest in the work of the Secretary's Advisory Committee on Regulatory Reform. In the report of the Secretary's Advisory Committee, those recommendations that might require congressional legislative action are denoted with an asterisk by the recommendation number.

Comparison of Regulatory Reform Provisions of H.R. 4954 and the Secretary's Advisory Committee on Regulatory Reform

H.R. 4954 Provisions and Section	Secretary's Advisory Committee on Regulatory Reform Recommendation Number
Establishment of coordinated survey demonstration project	116, 117
Extension of outpatient payment protection for certain rural hospitals	119
Hold harmless payments for outpatient departments in small rural hospitals	119
OASIS Task Force	54–64
Required issuance of guidance concerning discrimination against limited English proficient persons	134
Information Technology Demonstration Project	224–226
Local Coverage Determinations	69, 163
Issuance of regulations	16, 97, 185
Regular timeline for publication of final rules	16, 97, 185
Communication with providers	25–27, 30–31
Small provider technical assistance program	157
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Chairman JOHNSON. Administrator Scully, I was very pleased you discussed the forums that you have had. I think that has been very important to opening up the process for all of us. Your quarterly provider update has been very helpful, and begun to strengthen the give and take between the government and the people who provide the services.

Your Progressive Corrective Action Program is a help. I think we would have a ways to go in that regard. I would call your attention to page 6 of the American Medical Association (AMA) testimony. You don't have to look at it right now. Bottom line, the issue is that when government people come in and draw a sample, a physician ought to be able to give additional information so that the in-

terpretation of those cases is accurate. If the interpretation—it is a matter of interpretation anyway, and I understand there are some gray areas—but for physicians to say, wait a minute, you did not notice this part of the chart—that should be there.

For a consent decree process to get going without some evaluation of the base initial data is really a terrible frustration and a great unfairness in the current process. While you move towards addressing that, I do think the bill addresses it more accurately. That will be one point of discussion for us.

My question to you is—and I want you to answer briefly because I have one question for Dr. Wood and then we will move on—I think you need to tell us a little more clearly why you think we need to extend the time frames for the review process, because the time frames are really quite long. If you want us to extend this, I think you ought to direct yourself to that portion of your testimony for a minute.

Mr. SCULLY. I think the reality is that the time frames for the review process—right now we are looking at 440 days. Realistically, I don't think we can pull them off, to be honest with you. In the current bill you kick the next process—for a certain number of days the entire process is going to backlog, in my opinion, right back up to the Provider Review Board. The best intentions of speeding up the process, it just functionally cannot be done. We don't have enough money to pull it off.

Right now, in theory, I am supposed to take the $89 million that Social Security spends right now—they get $89 million from our budget directly, the trust funds, to do 8 to 10 percent of their caseload, which is Medicare. They have ALJs all around the country doing that.

We are supposed to take this on with exactly the same type of money as of October 1, do the same types of hearings, put all these processes in place and speed it up. I just don't think it is feasible at this point. I think the bill has obviously very good intentions of streamlining and speeding up the process. I just don't think the targets are, at this point, remotely doable.

If we can put this in place, get it up and running—essentially, outside of putting together a prescription drug benefit—which I hope I have the opportunity to do in the next couple of years—this is by far the biggest administrative challenge for this Agency, taking over Medicare appeals and making it work hopefully more smoothly than Social Security on essentially no budget now.

We would like to get it up and running, but with the timetables we have right now it is almost certain to just back up in the entire system and essentially backfire and possibly make it worse rather than better.

So, I hope we can put it in place with some more realistic time lines and it turns out we can actually do it efficiently and we can look at tightening them up in the future. I think realistically—the two major concerns I have are the time lines, and also the legislation requires us to put together 12 Quality Improvement Contractors. As I discussed, we could probably do four, have exactly the same functions, spend less money, and consolidate the operations. I think there are some technical changes that make it much easier for us to pull this off. It is a massive management job. We are tak-

ing on a whole new appellate process that has not existed in the Agency before. I hope with Social Security's help, I hope we can do it.

We are going to have more focus and energy and attention on Medicare. It is a relatively small part of their portfolio. In some cases, it has been a stepsister to their core function.

Chairman JOHNSON. We will talk further with you about it because 422 days is a long time. We will look at that more closely. Dr. Wood, thank you for your testimony and the time you have given to this process in the last year and a half in your Commission.

I was disappointed that you did not make more progress with the Outcomes Assessment Information System (OASIS). I appreciate there has been a 27-percent cut. Would you talk a little bit about my concern with OASIS and those things actually reflected in your comments in your summary. Particularly, I would like to hear about some of your broader statements, like the emphasis on changes in the statutory basis for reimbursement with existing constraints. It would reward quality outcomes and recognize the need for the balance of acute services with the growing need for services provided to the chronically ill and those providing long-term care.

That kind of recommendation, that kind of view, is embedded in your comments about where we need to go in the future, and it strikes me that my frustration with OASIS is part of that.

Dr. WOOD. I would agree. Actually, when we consider how some of these data sets were created, they were oriented towards specific programs or silos. The OASIS form could be considerably shortened if we had a way we could track beneficiaries throughout the system.

I will give a specific example. A patient who might have a fractured hip would be hospitalized, where there would be then a gathering of data that would be covered in Part A and separate data in the Part B payment system. If they then go to a nursing home, they might in fact have some data in the minimum data set (MDS). If they then go to home health, there would be something in OASIS.

None of those systems actually talk to each other. None of the providers have an opportunity to see what the providers before them have done. You could eliminate a substantial additional amount of information from OASIS if in fact there was a single data set that followed a patient through all of their specific interactions.

I think CMS operations could be improved as well in that regard. It would be particularly more effective in managing quality because you could then find opportunities for things that might happen in a hospital that have an impact, for example, on home health, or have an impact on nursing homes.

We have a hard time doing that. We are certainly appreciative of the emphasis on quality at CMS, but we just don't think the current systems are capable of providing that additional functionality. That is the basis of how we would approach that.

We had a short time, and there were a number of things we would like to finish. That would be one of our major objectives.

Chairman JOHNSON. Thank you.

Mr. SCULLY. I just want to jump in on OASIS, because I am not sure we discussed this. Knowing your concern about OASIS, I think OASIS is a great system. It was created by a contract that CMS/HCFA had with the University of Colorado. Months ago, I had people who wrote it and spent a day with me. They had to trim it back by two-thirds, I told them, or I was going to do it myself essentially. I spent a whole day with them. I was just asking because it got approved this week.

Some of the stuff that was in the OASIS requirements I think was done because somebody wanted it for their doctoral thesis. These people created this thing over years. This was their baby and they did not want to reduce any of it. I went through and we reduced it by 27 percent. I think we got the number of questions down from 96 to about 60. I spent a lot of time. I am pretty convinced we got it back to what you actually need for patient care.

The one complaint I still have and I'm thinking about changing is that we collect OASIS on every patient in the country. We actually use it for Medicare and Medicaid, but for the private sector patients we collect it and don't use it. I am saying we either have to find a way to use and disseminate it or quit collecting it. We spent a lot of time on OASIS. I think in the next few weeks you will see the fruition of the first level of work, a significant ratcheting back of the data collection on OASIS.

Chairman JOHNSON. Thank you very much. Mr. Stark.

Mr. STARK. Thank you.

Madam Chairman, Mr. Scully, sometime before or after dinner today, we are all going to have to vote on an omnibus appropriations bill which I am informed includes $54 billion over 10 years to "fix" the physician reimbursement question.

Can you tell us what you are going to do?

Mr. SCULLY. Well, it is not totally up to me, Congressman Stark. As you know, I have been saying from the first day that I discovered this glitch in the system—and you and I worked very much on this in 1989 when it was passed, so I have some pride in the Resource Based Relative Value Scale because I think it was worked pretty well. With the best of intentions, some changes remained in 1997 that limited our ability to fix the formula and it backfired. I discovered this last year in September.

Mr. STARK. Do you have a plan to take this $54 billion we are about to vote on and fix the system?

Mr. SCULLY. I have to get a ruling from Justice as to whether I have the power to do it. My sure intent, if I am told I am allowed to do it by Justice, I will do it as of March 1.

Mr. STARK. What will you do?

Mr. SCULLY. I don't actually believe it is the correct update—it is an OMB scoring matter.

Mr. STARK. The $54 billion will correct it if you are allowed to follow up——

Mr. SCULLY. The resulting update this year, instead of being negative 4.4, it will be plus 1.6 as of March 1.

Mr. STARK. So, if the U.S. Department of Justice doesn't let you do this——

Mr. SCULLY. Essentially the last version I saw of the omnibus bill is it basically keeps us from being sued over making the

change. I always thought this was a mistake. I wanted to fix it from the beginning.

Mr. STARK. The fix you have in mind would take care of it for next year with the——

Mr. SCULLY. If I have the authority to fix it, it would I believe correct some flaws in the formula that originated in 1998 and 1999 and get it back on the correct track for the next 10 years. You will still get, because of a variety of factors, most likely a negative update next year, but it would be smaller.

Mr. STARK. Have you determined what your prescription drug benefit plan will be?

Mr. SCULLY. No, we have not. I hope we are going to have something out soon.

Mr. STARK. The Secretary, the 26th of February, is coming to the House Committee on the Budget, and on February 27 is going to testify before the Senate Committee on Finance. Will you have your pharmaceutical plan by then?

Mr. SCULLY. The Secretary sure hopes so. We are working on it.

I will tell you that I think—I know there are a lot of disagreements between the House and Senate, the different parties, about where to go. It is pretty significant that the President has committed $400 billion over the next 10 years to spending on prescription drugs. Some people would like to spend more, but it is more than double what was in last year's budget. It is a strong signal coming from the President to work with Congress to get this done this year.

Mr. STARK. The advisory Committee recommended a number in their recommendation 192 that you have an interagency advisory committee to identify and enroll Medicare beneficiaries who are eligible for State assistance. Has that occurred?

Mr. SCULLY. Do we have an advisory committee? Yes.

Mr. STARK. That you have an interagency working group to identify eligible beneficiaries. Is that true?

Mr. SCULLY. I spent an awful lot of time on dual eligibles. We have spent a significant amount of time increasing enrollment. I am not sure what interagency task force.

Mr. STARK. Could you let us know?

Dr. WOOD. Yes.

[The information follows:]

Recommendation #192 reads:

Convene by September 1, 2002, with recommendations by July 1, 2003, and have a pilot ready to implement by September 1, 2003, an interagency working group consisting of CMS, State Medicaid Directors, and the Social Security Administration (SSA) to work on an improved system for timely and accurate identification, enrollment, and notification of dual eligibles.

The Secretary's Advisory Committee on Regulatory Reform adopted Recommendation #192 in June 2002 along with several other recommendations addressing dual eligibles. We are in the process of addressing these recommendations.

In addition to addressing notification, application, and enrollment of dual eligibles through the Secretary's Advisory Committee on Regulatory Reform, our evaluations of the Qualified Medicare Beneficiary (QMB) and Specified Low Income Beneficiary (SLMB) programs have taught us many things including the importance of personal assistance in the enrollment process. We are always looking for ways to improve these processes for our Medicare and Medicaid beneficiaries.

Mr. STARK. Dr. Wood, you had a number of recommendations to improve outreach and identify dual-eligibles. The President's proposal this year suggests that we require more, not less, documentation from lower-income individuals. As a matter of fact, they even are going to require more identification from second-graders to get the school lunch program. My son, when he goes to second grade, is going to have to take my income tax return along with his buddies to see whether or not he qualifies for assistance in his school lunch program.

You also recommended the State-based volunteer-run health insurance counseling program, SCHIP. Are you familiar with that?

Dr. WOOD. Yes.

Mr. STARK. Are you aware that CMS this year has deleted from the Medicare new handbook the telephone numbers to contact SCHIP? Is that the kind of progress that you think we should continue to make?

Dr. WOOD. No. In fact when we talked about some of these issues in our Committee, our concern was finding a way to make the enrollment processes simpler, especially for those who——

Mr. STARK. The quarrel is not with your Committee, but the Administration is not following your advice.

Dr. WOOD. That would not be consistent with the recommendations.

Mr. STARK. Okay. Further, your Committee's goal was not to address payment methodologies; is that correct?

Dr. WOOD. That is right.

Mr. STARK. In number 127, with the highest number of dissenting votes I might add, you specifically advocated changes to the Medicare+Choice payments. Now, while I was pleased to see you include risk adjustors in there, which the Administration disagrees with, why in that issue did you violate your principle?

Dr. WOOD. Actually, I think if you look at 127, we also identified that that was an area that would require considerable discussion and work at a legislative level, and it could not be readily fixed from a regulatory perspective. Indeed, the effort here is again to try to find a way that you can expand access and choice. That was the discussion that occurred at the Advisory Committee.

Mr. STARK. Thank you.

Mr. SCULLY. Mr. Stark, I spent a lot of time on SCHIPs. They do a great job. The decision was because we spent so much time and effort on trying to generate focus with seniors on 1–800–Medicare, which we frequently refer calls to SCHIPs, some of the consumer testing showed we confused people with so many phone numbers. I sat on those lines for hours. I think the SCHIPs do a great job. I meet with them regularly.

If we think that is somehow inhibiting the SCHIPs work, I would be more than willing to look at putting them back in the handbook. It was not done to discourage people from using SCHIPs.

Mr. STARK. Like the memo to the intermediaries——

Mr. SCULLY. I was not happy with that one. That was not accurate either. The way that was written, I could have sworn that somebody was writing it for publication in a newspaper. The way the memo was written, it said to spend all beneficiary education. That is in fact exactly not what happened; we didn't spend any for

education. We told the contractors not to undertake—if you look at the category it fell into, they could not do any new things like health affairs, any new outreach initiatives.

We did not do anything as far as not taking phone calls. Because we were operating under a continuing resolution and a funding freeze, we said no new health fairs in the communities, but we always took the phone calls, always answered the mail, always took responses.

I think it was a significant misrepresentation of what we are doing.

Chairman JOHNSON. Thank you. Mr. Ramstad.

Mr. RAMSTAD. Thank you, Madam Chair.

I want to thank both our distinguished witnesses for your testimony. I certainly want to welcome you, Dr. Wood, a friend from the Mayo Clinic in the great State of Minnesota. I want to thank you for your work as Chair of the Secretary's Advisory Committee on Regulatory Reform. You have performed valuable public service, and your recommendations are certainly important: 255 unfunded mandates. In total.

I commend the reading of the full transcript of Dr. Wood to every colleague on the Subcommittee. It is very, very well written, very informative, and I think can be very helpful as we seek to change some regulatory policy.

Dr. Wood, in your testimony you laid out some areas that require legislative solutions, really, for needed long-term changes. Two of the recommendations involve changing the statutory basis for reimbursement within existing expenditure restraints that would reward quality outcomes—which is music to our ears—and a more global system of payments that gives patients more choices and a greater ability, really, to be prudent in their health care choices as health care consumers.

It seems to me—and I have certainly discussed this a number of times with Administrator Scully and with colleagues here—the poster child for these needed changes is the highly flawed reimbursement formula for Medicare managed care. Improvements have been made, I realize, but the current adjusted average per capita cost formula is still based on the history of fee-for-service costs in different counties. It is arcane, archaic. I think it is unfair. It rewards high cost and inefficiency, and certainly penalizes States like ours, the State of Minnesota, that deliver high quality care in a cost-effective way.

I assume, Dr. Wood—and I don't mean to be presumptuous, but I assume that you agree that the current system for managed care reimbursement is flawed.

If so, what would your recommendations be, in 4 minutes or less, for reform?

Dr. WOOD. That is a pretty tall order, but I agree that there are very fundamental problems. The Committee's focus here was not to try to come up with a scheme of financing that would solve some of these problems, although our vision for the future is that we have to find a circumstance where we can provide information to beneficiaries so that they can make appropriate choices to meet their specific needs. Then, every beneficiary is somewhat different.

You can't have everybody trying to follow one program and only one set of rules and regulations, regardless of where you might be.

From our perspective, we have thought of a number of different ways that you could provide that choice. Fundamentally, having a way to get good, reliable, useful information in the hands of beneficiaries so they can make decisions about what options they had, what plan, whether it would be a managed care plan or an insurance plan or whatever; what gave them the access to physicians, the access to other services, drug benefits or whatever, and what gave them the range of services that would meet their particular health needs.

We are particularly concerned that as many seniors with chronic conditions get older, we have not organized a system to deliver very good chronic care or to help make the decisions about where you can get certain resources. We have to be able to do that.

Now, we are quite happy that there is a group of folks like you who can wrestle with the financing circumstances, and we were quite happy to think about just the delivery issues. As we get to those ultimately, coming back to Chairman Johnson's earlier question of why didn't we do more, in some areas we got to a point where it became apparent that we would have to do some fundamental change of the delivery system that would have some reimbursement implications.

That would have been something that would have simply been hard for us to overcome and would have delayed our ability in getting the recommendations in place. So, that is the reason we did not go into great detail in that regard.

Mr. RAMSTAD. It seems to me that the reimbursement implications are so pervasive in the system and that they certainly are part and parcel of reform, and certainly any recommendations that would be forthcoming from you or your group would be very much appreciated. Thank you again for your leadership on the important Advisory Committee on Regulatory Reform.

In the remaining couple of minutes I have, I just want to ask Administrator Scully, we have talked many times about the unconscionably long coverage, coding payment, and appeals decision process with respect to medical devices, medical technology, the bureaucratic delays, and the poor interagency coordination, which certainly don't serve the patient or the system well.

I am just again asking that you will work with us on the Medicare Innovation Responsiveness Act to streamline the system and better coordinate the various functionaries, those who work on these issues. We really need to improve accountability, openness, and coordination. So, I am hopeful that you will work with me on this legislation this year, and we can get even more of it passed than we did last year.

Mr. SCULLY. Absolutely. I also hope you will find that the people—and this is our chief doctor on the staff—have been much more open and willing to meet with people on the outside. I have pushed them to do that. People are not always going to make our decisions. We have to make tough coverage decisions.

Mark McClellan is a new administrator and a good friend. We have talked a lot about one of the frustrations we have is where FDA would spend a couple of years looking at a product or device,

and then they would have to start all over again with CMS. Some of that is statutory. FDA cannot share all their information with us. We have started talking and getting ahead.

For example, we actually approved drug-eluting stents, something Secretary Thompson and I got very involved with. The FDA still has not approved it, but we actually went ahead and approved it. We felt that was a device that was going to improve the delivery of health care in a major way, so we actually went ahead and created a code to pay for it as of April 1, on the assumption that FDA will approve it. I don't think they have, but I think they will in the next month or so.

We have tried to answer the critics about some of the slow-moving bureaucracy, of having to wait a couple of years with FDA and then start again from scratch with CMS. I think we have made some significant changes. We have to make a lot of tough calls on drugs, devices, international classification of diseases, which we discussed before the hearings. They are complicated issues that involve billions of dollars and lots of patients, and we take them very seriously. I think we have gotten much faster and better.

Mr. RAMSTAD. Thank you. Just a final comment, Madam Chair, if I may.

You have created, Administrator Scully, an atmosphere of openness and optimism at CMS. For that we are grateful. There is hope that even more changes can be made to streamline the process. You have made significant steps under your leadership. Thank you for that.

Mr. SCULLY. Thank you.

Mr. RAMSTAD. Thank you, Madam Chair.

Chairman JOHNSON. Thank you. Ms. Tubbs Jones has yielded to Mr. Kleczka because he has to go back to Florida. Mr. Kleczka.

Mr. KLECZKA. Thank you. I concur in the remarks of Mr. Ramstad when it comes to your service, Mr. Scully. I have really enjoyed working with you since you have taken over the helm of CMS. You have been responsive, even though I recognize that you are not exactly a cheerleader for the Medicare program, but you have been very responsible.

With that being said, let me attack you now. Congressman Stark talked a little about the physician payment fix, the $54 billion in the bill we are going to be taking up today. Do you anticipate that the Administration is going to come back for some further legislative fix later this year?

Mr. SCULLY. On the physician payment thing specifically?

Mr. KLECZKA. Right.

Mr. SCULLY. I don't think that has been decided. I think the update would be 1.6 for the rest of the year if we make the change. It would put the formula back on the right track, I believe.

It obviously depends a lot on many complicated factors, including gross domestic product growth, physician spending. The reason we enacted it in 1989—and I was then the OMB guy who spent a lot of time with Mr. Stark passing it—was because physician spending was growing 15 percent a year. The idea was to control volume and tie volume to performance and various categories together.

I think a negative 5.4-percent update last year was incorrect and should never have happened. This year a negative 4.4 percent

would have been unconscionable. I worry about it. I have six physicians in my family, and I worry about it because we would have had access problems with patients. I think we had not seen them yet, but I have no doubt they were coming.

I was very concerned that we would start seeing physicians not taking Medicare patients. If physicians want to be our partners in the long run for the program, they have to expect a reasonable reimbursement. I think it was not a provider giveback, in my opinion. It was a mistake. I don't believe anyone ever really expected us to have negative updates in payments for physicians.

Mr. KLECZKA. Clarify in my mind why you need a Justice Department ruling. Do you feel that there are going to be some lawsuits emanating from this change?

Mr. SCULLY. There have been lawsuits. In the Clinton Administration, there was a series of lawsuits between the AMA and the Administration over this exact issue. It was decided that the interpretation at the time was correct, however, we misinterpreted it.

Essentially I have wanted to fix this for a year and a half. The Justice Department's ruling, correctly I believe, was that we did not have the administrative authority to do it. When the statute was changed in 1997, it was tightened in a way I did not have the administrative authority to change it.

What the language in the omnibus bill says essentially is that our decisions are not reviewable. It does not say we should do it, it says we cannot be sued if we do it. I have not yet gotten the ruling from Justice but my anticipation, having discussed it with them, is that if it does pass that we will be putting in a reg.

I actually had to tell the contractors yesterday what the rate was, and I have held off as long as I can. I am hopeful it is going to be 1.6, not minus 4.4. I expect if it passes they will let me go ahead.

Mr. KLECZKA. Is the language in the bill we are voting on today going to do the job, or are you still in doubt?

Mr. SCULLY. It will probably do the job, in my opinion.

Mr. KLECZKA. Probably?

Mr. SCULLY. I have every expectation when it passes out and we get a final rule from the Justice Department, I have the expectation we will do a positive update.

Mr. KLECZKA. I will leave questions on prescription drugs to my colleague, Ms. Tubbs Jones. Let me ask one question on your testimony. On page 6, you talk about the Local Provider Education and Training (LPET) Program. You indicate that this year's funding will be doubled. Can you give us a figure? What dollar amount are we talking about? The bottom of page 6, Tom.

Mr. SCULLY. Give me one second to put my—I didn't need this last year. I am trying to look at my budget.

Mr. KLECZKA. This year we doubled funding for the LPET.

Mr. SCULLY. It is not a chart I have. I think it has been doubled. The overall contractor budget in the 2004 budget is $1.776 billion, and I believe the provider education amount is somewhere around $100 million. I will have to get that for you.

Mr. KLECZKA. Is that the doubled amount?

Mr. SCULLY. The doubled amount. I am not certain. I will have to check.

Mr. KLECZKA. The quote here, Mr. Scully, is, "this year we doubled funding."

Mr. SCULLY. Yes. We doubled funding in the budget for provider education and training.

Mr. KLECZKA. That amount is $100 million?

Mr. SCULLY. I believe that is about right. I should know that off the top of my head. I apologize.

[The information follows:]

As part of our efforts to improve performance through provider education and outreach, we have expanded our Local Provider Education and Training Program, also known as the L-PET program. Contractors spent $17,779,500 on L-PET activities in FY 2002. In FY 2003, we have distributed $35,243,000 to the Fiscal Intermediaries and Carriers. L-PET is targeted to be a response to problems identified through the review of claims. Providers are receiving more education related to their claims submission. Clinicians deliver most of the education, and respond to specific coverage or coding issues. Contractors meet with providers in group settings, individually, or communicate using the Internet. As a result, our contacts with the provider community are more collaborative.

In addition to L-PET, we have taken many other steps to improve provider education, such as through interactive websites like MedLearn, satellite broadcasts, conferences and town hall meetings, and Open Door Forums.

Mr. KLECZKA. The last question is on the contracting. You indicated the 5-year rebidding might not be the best time frame. Do you have a suggestion other than that?

Mr. SCULLY. Some of this is a blend of the institution's views and mine. I am not actually uncomfortable with the 5- to 6-year rebidding.

I think because of the financing, the staff is concerned that some of the contracts—there may be some States that have done a great job over the years. The staff is concerned you have to rebid every contract every 5 or 6 years, including the ones that have done a terrific job and stayed, relatively smaller States. It might be better to have the flexibility to do it every 7 or 8 years. It is more a matter of resources. If we are forced to rebid a contract every 5 years, it might not be the best prioritization of resources.

I personally want to tell you, I am not uncomfortable with doing it every 5 to 6 years. I think rebidding contracts is a good idea.

Mr. KLECZKA. You are trying to reduce the number of intermediaries. How are we going to go about doing that, just with the contracting price, the lowest type of system?

Mr. SCULLY. Yes. We bid them out and we would pay them differently and we would try to make them compete for contracts regularly, and try to get the number down to 20 or 25.

A lot of our contractors are in Wisconsin; Wisconsin physicians and United Government Services, which is a subset of BlueCross Wisconsin or Cobalt. They happen to be two of our biggest and best. My guess is they get a lot more work out of this because they have been two of our best contractors.

I think what is happening now, because a lot of the BlueCross plans are going for profit, as you know in your State, they don't look at the contract business as being such a great business. A lot are getting out of it. What you have found is a consolidation of BlueCross programs, and other people who want to be in this for the long haul. Fortunately, United Government Services seems to

be one of them. We would like to find people who want to be partners for 20 years. We would like to give them work, have better consistency, and run the program more efficiently. We think the best number is between 20 and 25 contractors, not 47.

Mr. KLECZKA. Dr. Wood, do you have a comment on that?

Dr. WOOD. From a personal perspective, I would share that observation. There are some of my colleagues who believe we have to remain fragmented into small areas. The overall objective should be a high quality of service. I happen to be an area covered by Wisconsin Physician Services. I deal with medical directors that are in different States, but it works reasonably well.

Mr. KLECZKA. With two major contractors coming from Wisconsin, and I coming from Milwaukee, Wisconsin, home of Cobalt, I happen to agree with both you gentlemen. Thank you, Madam Chair.

Chairman JOHNSON. Mr. Crane.

Mr. CRANE. Tom, in the short time that you have been with the Agency, you have made considerable progress in giving beneficiaries information, nursing homes and other providers. Can you highlight one of the changes that you believe made a significant difference in the lives of seniors?

Mr. SCULLY. Well, the one we made the most traction on so far is nursing homes. I think it is not just seniors. I really believe that probably the number one place I got complaints about quality and about senior concerns were nursing homes, coming to the job.

We also have extensive data on every nursing home patient in the country through MDS. It wasn't easy, it was difficult, but we had the data to put together fair tracking of quality between nursing homes.

I also think, in the last year, when I started out, I think the Service Employees International Union has been great—which is the biggest union—the nursing homes, for profit and non-profit, and the consumer groups did not have great relations, did not talk to each other much. In the process of doing these quality measures, they worked together incredibly well. They came with a consensus on quality measures. We got them done in less than a year. We now have all 50 States with published quality measures. I think it has dramatically, in my opinion, improved the relations between the various groups involved in nursing homes.

I guess the criticism I got to begin with is, no senior would ever understand the article in the Chicago paper rating nursing homes. Maybe they don't. What it has created is an enormous buzz, in my opinion, around the nurses, around the employees, around the community, in the nursing homes, to talk about quality, and who has the best bed sore problem or the worst bed sore problem, the worst activities of daily living problems. It has created a whole level of discussion around nursing home quality that I think has dramatically improved the awareness of the people that are in the nursing homes and their families.

I think it has had a big impact already, and I think it has just completely changed the dynamics between the patients, the nurses and their unions, the nursing homes, much for the better. I think it has worked out very well.

Mr. CRANE. We understand that both CMS and the Secretary's task force supported elimination of local intermediary utilization restrictions for emergency visits. When will that important change for beneficiaries take place?

Mr. SCULLY. Local intermediary restrictions on emergency room visits?

Mr. CRANE. Yes.

Mr. SCULLY. Mr. Crane, I am not sure. I will have to check on that and get back to you. I apologize. I wasn't aware that we still had local intermediaries making restrictions on emergency room visits.

[The information follows:]

The Secretary's Advisory Committee on Regulatory Reform did not address local intermediary utilization of emergency services.

On December 20, 2002, in response to a request by state officials, CMS sent a letter to state Medicaid directors to make sure states understood managed care plans could only place the same restrictions on beneficiaries—related to utilization of emergency services—as those in fee-for-service programs.

Medicaid law requires that enrollees in Medicaid managed care plans can get emergency care using the "prudent layperson" standard, and the right to post-stabilization services when the patient goes to a hospital that is not in the managed care organization's network. States may limit the numbers of emergency room visits paid for, but the Emergency Treatment and Active Labor Act (EMTALA) requires hospitals and emergency rooms to screen and treat all individuals, including Medicaid enrollees, who come to an emergency room for health care services.

The law does not distinguish between health care services provided in emergency rooms to Medicaid beneficiaries in either fee-for-service or managed care. States do have the authority to set the limits on how much and how often Medicaid will pay for someone to get care in an ER. Five states have established limits in their Medicaid fee-for-service programs, to encourage patients not to use the emergency room as their doctor's office. To ensure uniformity and equality for beneficiaries, they may also include such limits in Medicaid managed care plans. However, no one who is in need of emergency care will be turned away from an emergency room.

CMS's December 20 letter is consistent with those provisions. Hospitals and emergency rooms must continue to provide care for emergency services. If an emergency service exceeds the limit that is established in a state's benefit package, the service will still be furnished but the state may not have to pay for that service. This is the identical policy available to Medicaid beneficiaries who are not covered by a managed care plan.

Mr. CRANE. Dr. Wood, the task force under your direction covered an extensive amount of ground and made many specific recommendations. What overarching theme or conclusion would you draw from your experience?

Dr. WOOD. I think it would be most important to recognize that many of the problems that exist probably reflect that there are a number of different programs that have developed in almost a silo-like fashion, and that as you make law and regulation for one, you then create barriers to access and transition between them.

If we would go at it the other way and think about what do you need to do to provide the spectrum of services for beneficiaries so that they can use them when they need to, and that there is almost a seamless integration, we could substantially improve the functioning of the system.

I think we would also find not also operational but quality savings as well, because you could get back an ability to understand what is in the data about where are the best places to get things done, and we could identify opportunities for improvement in the

system; coming back to a concern that I know Chairman Johnson has, that we have not been good at continuous improvement. That requires good measurement and data systems to be able to do that.

Mr. CRANE. Thank you.

Chairman JOHNSON. Ms. Tubbs Jones, welcome to our Subcommittee.

Ms. TUBBS JONES. Thank you, Madam Chair, for allowing me to participate in the Subcommittee. Good afternoon, Dr. Wood, Mr. Scully.

My first Committee hearing on health care. I come from the great city of Cleveland, Ohio, home of the Cleveland Clinic, University Hospitals, Metro Hospital, St. Vincent's, and the list goes on. So, even though I am not on the Subcommittee, it is a very, very important issue for my constituency, and I am going to try and be quick.

Let me ask you, Dr. Wood, in the course of the work that you did at the study, what did people say to you about a prescription drug benefit?

Dr. WOOD. Going around the country and listening to public comment, that was often one of the most significant issues that arose. The perspective of people that would come and talk with us really reflected what they considered to be their specific needs.

If you consider that most older Americans have one or more chronic conditions, it is hard for them to get successful treatment of those chronic conditions when they don't have access, or they have limited access, or they are having to make choices about prescription drugs which are an important part of the care of chronic conditions.

We also heard concerns about access to providers, rules that would limit opportunities to get even things like durable medical equipment in an easier fashion. Those are all very complex circumstances, but I think they reflect that we haven't probably been as good as we could be in keeping the Medicare problem modernized to meet the needs of a growing number of people who have chronic conditions that require considerably more support than was the case when the program was designed many years ago and we were dealing mostly with acute illnesses.

Ms. TUBBS JONES. What would you recommend?

Dr. WOOD. Well, actually if you go back to the long-term recommendations of our Committee, and look at some of the unresolved issues, I think that you would see that we would like to see a reorganization of the program that would allow you to meet those ongoing chronic conditions. I might ask you——

Ms. TUBBS JONES. Specifically with regard to a prescription drug benefit. I am sorry.

Dr. WOOD. Well——

Chairman JOHNSON. This hearing is not on the prescription drug bill. It really is on how the regulatory aspect of Medicare can be used to improve the quality.

Ms. TUBBS JONES. Clearly, in his own testimony, Madam Chair, if you would allow me, he said that was the largest concern of the people that he talked to as he was out there. I just thought that since he was an expert, that I might make use of his experience on the issue. If you want to restrict me, so be it.

Chairman JOHNSON. I am not going to restrict you. The point is that we are going to have lots of hearings on that subject, but the testimony on this hearing was really excellent. Proceed, Dr. Wood, any way you want. I don't want to get too far off.

Ms. TUBBS JONES. That is my last question of him.

Dr. WOOD. I would simply answer that we heard that as a Subcommittee. In fact, the testimony is on the Web site. That was not a subject that was in our charge. So, we simply marked that as something that would need to be covered by a legislative solution.

Ms. TUBBS JONES. If I can be clear on my question. You are a physician. You practice law.

Dr. WOOD. Yes.

Ms. TUBBS JONES. What would most benefit your clients?

Dr. WOOD. Not only my clients, but the people who came to talk to us; they would like a prescription drug benefit.

Ms. TUBBS JONES. Okay. I am going to leave that alone. Mr. Scully, how are you, sir?

Mr. SCULLY. Great. You can ask me that.

Ms. TUBBS JONES. I am looking forward to having the opportunity—you haven't had time. You all haven't figured that out yet from last week. That is the answer I kept getting. You haven't worked it out yet.

Mr. SCULLY. We are getting close.

Ms. TUBBS JONES. Who do I contact in your office to set up some programs for the nursing homes and health care providers and so forth in my congressional district if I wanted to help facilitate responses to questions with regard to providing—to dealing with Medicare issues and Medicaid issues?

Mr. SCULLY. You can certainly talk to me. I have mentioned I have been in 47 congressional districts in the last year. Not quite. I am happy to go to Cleveland whenever it works out. I have done a lot of both sides of the aisle. I think that I have a number of special assistants, Marty Corry, who is here today who works with me and will be happy to help you out.

Ms. TUBBS JONES. I don't have but a second left, but let me ask one other question of you. In this appellate process—in one of my prior lives, I was a judge. I am curious are there expedited appeals for emergency situations, or is there a process?

Mr. SCULLY. There is a process. I think there is a way for them to be sped up through Social Security, but there is no specific process for that. It is one of the reasons, to be honest with you, why we are interested in taking it over in Medicare, because I think we will be much more sensitive to Medicare appeals.

I have inserted myself in a bunch of them. There doesn't seem to be a process beyond that for people with acute problems.

Ms. TUBBS JONES. Real quickly, Madam Chair. In some of the other Federal agencies, what they have done is fast-tracked certain types of cases. I used to work for the Equal Employment Opportunity Commission, and we did a fast track on certain types of cases. As you are going through the process, I would ask you to maybe consider what types of cases might be fast tracked or expedited in some way. I thank you, Madam Chair.

Chairman JOHNSON. I thank the panel for their comments. There will be a lot of discussion of particularly some of the con-

tractor issues and the medical director concerns. There is a difference between the technology issues and the other aspects of regional administration, or at least some of the other aspects of regional administration that may not yield themselves to quite such large groupings as ultimately four or five contractors.

So, we are going to get into that. I hope that your people will look carefully at some of the testimony that we are going to hear today from the emergency physicians, from the home health agencies, and some of the small ones where repayment takes a little different situation and it takes on a different color than in some of the other areas.

The physicians are going to testify that the extrapolation issue isn't consistent across the country, to say the least. So, we do have a lot of work before us, both on implementing the recommendations that have been made and dealing with the provisions in the bill, but also enlarging on them. We must not miss this opportunity to enlarge upon them. Thank you very much.

Mr. SCULLY. Can I say one thing, because I didn't know this. There is an expedited appeals process for discharges from a hospital, for someone to appeal the hospital discharge. It is expanded in the HCFA provisions that Chairman Johnson worked on for discharges from nursing homes and home health.

Chairman JOHNSON. I think Mrs. Tubbs Jones's underlying comment that as we look at the appeals issue, we should look for a way we can break it up, or have certain kinds of processes at the beginning so that so many don't go to appeals. This 422 days is really a question—you know. Untimely justice is often not justice at all. So, we will talk with you about that much more extensively.

It is a point of considerable difference between the bill and the Agency, I wanted to at least bring it up at the hearing. Thank you very much.

Mr. SCULLY. Thank you.

[Question submitted to Mr. Scully from Chairman Johnson, and his response follows:]

Centers for Medicare & Medicaid Services,
200 Independence Avenue, SW
Washington, DC 20201

Functional Equivalence

Q: I understand it is current agency policy is not to introduce new matter in final regulations. In the oupatient final rule, you established new criteria called "functional equivalence" (same price for drugs that serve the same biological process). When did CMS allow for public comment on this new standard?

A: Functional equivalence is a term CMS developed as a result of comments received during the comment period on the notice of proposed rulemaking on the 2003 update for Medicare's outpatient prospective payment system to describe the relationship between Aranesp and Procrit. As we explain in the final rule, it became apparent that darbepoetin alfa, while not structurally identical to epoetin alfa, uses the same biological mechanism to create the same clinical effect in the body. To encapsulate this phenomenon, we used the term "functional equivalence."

The term "functional equivalence" is not a criteria or a standard, but a descriptive term used to capture a relationship between two drugs. As you may know, the comment period is a vital part of the process we use to issue every regulation. We place high value on all comments we received from interested parties. In fact, it was through comments received during the comment period on the proposed rule regarding the relationship between Aranesp and Procrit that led us to employ the term "functional equivalence."

Chairman JOHNSON. Now we will convene the concluding panel. I have read your testimony. It is really excellent. I hope some of the other Members will be able to get back. If not, I am pleased to know that their staff are here, because you do raise in your testimony a lot of very fundamental questions and make some very good suggestions as to how to go forward.

We do have quite a long panel. We are going to give each person 5 minutes. You know the rules. Your whole testimony gets submitted for the record. You get 5 minutes and then we get to question.

I do want to say that if there aren't more Members to question, I am going to invite you to comment on one another's testimony too, because this isn't about silos, this is about a system. So, a number of things that some of you are saying in one area, the others might want to comment on as well. Michael Luebke, President of Verizon Information Technologies. I am going to take you in the order that you are at the desk. Mr. Luebke.

STATEMENT OF MICHAEL LUEBKE, PRESIDENT, VERIZON INFORMATION TECHNOLOGIES, INC., TAMPA, FLORIDA

Mr. LUEBKE. Good afternoon, Chairman Johnson, Ranking Member Stark, and distinguished Members of the Committee. I would like to thank Congresswoman Johnson for the opportunity to contribute to the process of continuing to improve upon and build a better health care system for our citizens.

My name is Mike Luebke, and I am President of Verizon Information Technologies, a wholly owned subsidiary of Verizon Communications. My organization is responsible for the commercial sales and marketing of select Verizon telecommunications, information technology, and health care products and services. Our parent company, Verizon Communications, is a premier data, video, and voice network services company. We employ nearly 250,000 people in 40 Nations.

Today I would like to take a few moments to tell you why we support your contract reform initiative and why it is beneficial to Medicare administration.

Frequently I hear people say, I didn't realize Verizon was in the health care business. The fact is it is a very natural fit for us. The information technology demands of a telecommunications company are very similar to the information technology demands of the health care industry. Verizon's extensive health care experience is derived from providing information technology services to Medicare carriers and intermediaries, commercial managed care insurers, and State government Medicaid programs.

Verizon is one of the largest and most efficient technology companies in the United States and a leader in information processing and security. We have enjoyed lengthy relationships with our health care customers. Some of them have been leveraging our information technology solutions for nearly 15 years. We have a successful track record of providing information technology services to many premier health care organizations.

Our data centers process nearly 1 billion health care transactions a year. In addition, we are responsible for processing the transactions for close to 20 percent of all Medicare Part B claims. We are considered throughout the health care industry as a quiet and effective leader for information technology services, security, and efficiency.

Verizon has been following the development of contractor reform since its inception, and I applaud Representative Johnson for her ongoing efforts.

Verizon supports the Committee's Medicare Regulatory and Contractor Reform initiatives. These initiatives will create a competitive environment that encourages innovative companies like Verizon to offer their significant core competencies in information technology to the government.

The result of opening competition and focusing on core competencies brings with it the best in commercial practices and pricing, continuous technology innovation, and an overall lowering of administrative overhead.

Recent world events have placed, very appropriately, a renewed focus on security and, in particular, information security. Through contractor reform, companies like Verizon will be able to compete to offer to CMS and all Medicare beneficiaries the benefits of a secure environment for their data. For example, Verizon has in place for its own business a hardened data center environment, protected from power outages, natural disasters, and unauthorized access. In addition, our data center security already exceeds the proposed HIPAA requirements. These two examples demonstrate how CMS could take advantage of features that Tier I data centers such as Verizon have put in place to gain cost efficiencies.

We are anxious to bring the Federal Government the very best in proven commercial practice. With contractor reform, I strongly believe that Verizon, along with other qualified companies, will be able to dramatically enhance CMS's ability to efficiently and effectively provide state-of-the-art claims processing and information security.

For example, the contractor reform initiative would allow the government to consider the viability of carving out and consolidating information technology and data center functions. This is consistent with the trend in the commercial sector and has accounted for significant savings and process improvements.

I believe that this legislation will provide more companies like Verizon with a significant opportunity to contract directly with CMS. The CMS will then have access to the leading companies in information technology and security. The passage of this legislation will allow companies to assist the government to meet or exceed the goals set forth by Congress and HHS over the next several decades.

Opening the doors for competition will unleash the power and skills of the private sector, resulting in the application of state-of-the-art technology and lower administrative costs, and will allow more commercial companies to participate and bring the best commercial practices in information technology to the government.

The passage of contractor reform initiatives will be one of the most significant contributions to reforming Medicare. The opening

up of competition to organizations that have the ability to converge and integrate a multitude of technology advances will allow and provide incentives for future progress and cost efficiencies.

I thank you for the opportunity to speak with you today. I look forward to any questions that you may have. Thank you.

[The prepared statement of Mr. Luebke follows:]

Statement of Michael Luebke, President, Verizon Information Technologies Inc., Tampa, Florida

Good morning, Chairwoman Johnson, Ranking Member Stark and distinguished members of the Committee. I would like to thank Congresswoman Johnson for the opportunity to contribute to the process of continuing to improve upon and build a better healthcare system for our citizens.

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Recent world events have placed—very appropriately—a renewed focus on security and, in particular, information security. Through contractor reform, companies like Verizon will be able to compete to offer to CMS and all Medicare beneficiaries the benefits of a secure environment for their data. For example, Verizon has in place for its own business a hardened data center environment, protected from power outages, natural disasters, and unauthorized access. In addition, our data center security already exceeds the proposed HIPAA requirements. These two examples demonstrate how CMS could take advantage of features that tier one data centers such as Verizon have put in place to gain cost efficiencies.

We are anxious to bring to the federal government the very best in proven commercial practice. With contractor reform, I strongly believe that Verizon, along with other qualified companies, will be able to dramatically enhance CMS's ability to efficiently and effectively provide state-of-the-art claims processing and information security. For example, the contractor reform initiative would allow the government to consider the viability of carving out and consolidating information technology and data center functions. This is consistent with the trend in the commercial sector and has accounted for significant savings and process improvements.

I believe that this legislation will provide more companies like Verizon with a significant opportunity to contract directly with CMS. CMS will then have access to the leading companies in information technology and security. The passage of this

legislation will allow companies to assist the Government to meet or exceed the goals set forth by the Congress and the Department of Health and Human Services over the next several decades.

Opening the doors for competition will unleash the power and skills of the private sector, resulting in the application of state-of-the-art technology and lower administrative costs. It will allow more commercial companies to participate and bring the best commercial practices in information technology to the government.

The passage of contractor reform initiatives will be one of the most significant contributions to reforming Medicare. The opening up of competition to organizations that have the ability to converge and integrate a multitude of technology advances will allow and provide incentives for future progress and cost efficiencies.

I thank you for this opportunity to speak with you today. I look forward to answering any questions that you may have.

Chairman JOHNSON. Very impressive. Mr. Fay.

STATEMENT OF TONY FAY, VICE PRESIDENT, GOVERNMENT AFFAIRS, PROVINCE HEALTHCARE COMPANY, BRENTWOOD, TENNESSEE, ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Mr. FAY. I am Tony Fay, Vice President of Government Affairs for Province Healthcare Company in Brentwood, Tennessee. I am here today on behalf of the American Hospital Association's nearly 5,000 hospital, health system and health care provider members. Thank you very much for this opportunity to discuss regulatory relief for the health care providers of America.

Province Health Care owns and operates 20 acute care hospitals in rural markets in 13 States. We also provide management services to 36 primarily non-urban hospitals in 14 States, and we are deeply committed to developing hospitals and health care systems that serve the unique needs of rural and nonurban communities.

We are very pleased that again this Congress, you and your colleagues, recognize the dilemma that health care providers face in complying with the myriad of health care rules and regulations. During the 107th Congress, the House overwhelmingly passed H.R. 3391, the Medicare Regulatory and Contracting Improvement Act. This included a number of recommendations from the AHA's Regulatory Reform Task Force.

Thanks to your efforts and those of HHS Secretary Tommy Thompson, we are making great progress in relieving some of the regulatory burdens facing health care providers and Medicare beneficiaries. I had the deep pleasure of serving on Secretary Thompson's Advisory Committee on Regulatory Reform, a Committee which the AHA fully supported. This provided the opportunity for a firsthand look at the impact that the regulatory burden has on patient care and beneficiaries.

The Committee's report to the Secretary included 255 detailed recommendations, some of which are currently being implemented by CMS and HHS. A number of these were heartily endorsed this AHA. Just to enumerate a few:

One, adopting recommendations on the Emergency Medical Treatment and Active Labor Act (EMTALA), such as creating an advisory committee and amending the local medical review policy as it relates to emergency department services.

Two, streamlining the Minimum Data Set on OASIS, thus reducing the amount of staff time spent on these assessments; and, conversely, increasing the amount of time spent on patient care.

Three, revising policy for collecting and using Medicare Secondary Payer information.

Four, amending the HIPAA privacy rule and changing certain consent regulations which would have hindered patient care.

Five, addressing key concerns of rural providers.

These revised policies are helping to alleviate the burden on caregivers. Madam Chair, working with you and your colleagues and the HHS, we can go further to reduce the red-tape burden on caregivers while strengthening our basic health care system.

We urge this body to consider the following additional areas for regulatory reform:

First, reduce the size and complexity of the Medicare Cost Report and modify or eliminate its Medicare cost-specific accounting principles. The Cost Report is a relic of a bygone era, used prior to the implementation of the current Prospective Payment System (PPS).

Second, recognize that EMTALA should not apply to inpatients. Once a person is admitted as an inpatient, the hospital has actually taken on responsibility far more than is required under EMTALA.

Third, allow providers direct access to court to challenge decisions made by CMS. While I am not an attorney, I can tell you that currently the only way to appeal decisions made by CMS is to fail to follow the rules, become terminated from the program, and then appeal to the courts for relief. No other Federal agency operates in this manner.

Fourth, further simplify the data collection process that uses the OASIS and MDS forms, and try to harmonize the forms so that they can be used interchangeably between sites of service.

Fifth, establish commonsense guidelines for regulations. Regulations should be clear, they should be unambiguous, and they should be well documented. They should also enable better communications between all parties involved—regulators, health care providers and patients—and they should be cost effective.

Last, regulations and the related interpretive guidance that often follows them should meet the following criteria. They should establish a safe haven for innovation and encourage the pursuit of excellence through best practices. They should be applied prospectively with no disruption to patient care activities, and they should include updated interpretive guidance and CMS manuals which are updated on a commonsense publication cycle.

Madam Chair, our first priority is to our patients. While some regulations contribute to this goal, others drain away much needed resources, placing a strain on our hospitals and the men and women who work there. We believe the health care field should be regulated, but in a commonsense fashion that allows health care providers to do what they have been trained to do: care for the ill and injured of our communities.

Thank you very much for your time today. On behalf of the members of the American Hospital Association and its members, we look forward to working with you and your colleagues further to provide relief from regulatory burden.

[The prepared statement of Mr. Fay follows:]

Statement of Tony Fay, Vice President, Government Affairs, Province Healthcare Company, Brentwood, Tennessee, on behalf of the American Hospital Association

Good morning, Madam Chairman. I am Tony Fay, vice president of government affairs for the Province Healthcare Company in Brentwood, Tennessee. I am here today on behalf of the American Hospital Association's (AHA) nearly 5,000 hospital, health system, network and other health care provider members. We're pleased to be able to testify on proposed regulatory relief and reforms for the health care field.

Province Healthcare owns and operates 20 acute-care hospitals in non-urban markets in 13 states. We also provide management services to 36 primarily non-urban hospitals in 14 states. At Province, we are committed to the development of hospitals and health care systems that serve the unique needs of non-urban communities.

Regulatory Progress

Patients are the priority—no matter the time, no matter the condition and no matter the hospital. Our facilities are open 24 hours a day to provide health care services to our friends and neighbors in the communities where we work and live.

But every time the nurses, physicians and other health care workers care for a patient, a host of regulations and statutes govern their very actions, especially if the patient is a Medicare or Medicaid recipient. More than 30 agencies oversee some aspect of that health care delivery process—and that's just at the federal level. State agencies add yet another layer—or two. More than 130,000 pages govern the Medicare system—a sheaf of paper three times larger than the IRS Code and its federal tax regulations.

Unfortunately, these regulations and statutes do not always enhance the patient care experience. In fact, quite the opposite. They absorb valuable time and resources—time that could be spent caring for the next patient to come through the emergency department doors.

We are gratified, Madam Chairman, that again this Congress, you and your colleagues recognize this dilemma and are examining the regulatory maze that health care providers face. During the 107th Congress, the House unanimously passed H.R. 3391, the Medicare Regulatory and Contracting Improvement Act, which included a number of regulatory relief initiatives proposed by the AHA's own Regulatory Reform and Relief Advisory Committee. While the Senate introduced similar legislation, it did not pass.

HHS Advisory Committee on Regulatory Reform

But we're still a long way ahead of where we started, thanks in part to you and your colleagues and the interest you've taken in an issue that directly impacts our patients, and thanks in part to Health and Human Services (HHS) Secretary Tommy Thompson and his own Advisory Committee on Regulatory Reform.

His committee, on which I served, consisted of health care professionals, academics and others committed to ensuring quality patient care with less burdensome regulations. The AHA fully supported this committee, and with our member hospitals, provided opportunities for the Advisory Committee and HHS to see first-hand the consequences of regulatory burden on patient care. The Advisory Committee's report to Secretary Thompson included 255 recommendations, many of which were adopted—some of which are currently being implemented. And a number of these recommendations were heartily endorsed by the AHA, such as:

- Adopting recommendations on the Emergency Medical Treatment and Labor Act (EMTALA), including establishing an advisory committee and ensuring that local medical review policies for outpatients services are not applied to emergency department services.
- Streamlining the Minimum Data Set (MDS) for most nursing homes by convincing the Centers for Medicare & Medicaid Services (CMS) to reduce the size of the MDS, and thereby reducing by half the staff time spent on completing it.
- Convincing CMS to streamline the OASIS form by eliminating 27 percent of the information items currently reported by home health agencies and two of the 10 assessments currently required, reducing the time spent by nurses on OASIS data reporting by 25 percent.

- Urging CMS to revise its policy for collection of Medicare Secondary Payer information from every 30 days to every 90 days for recurring outpatients services in hospitals, and from every 60 days to every 90 days for hospitals serving as reference labs.
- Changing the Health Information Portability and Accessibility Act privacy rule so that patients will no longer have to wait to receive care until a consent form is signed, and providers will have ready access to needed patient information in order to continue to provide timely, quality care.
- Addressing key concerns of rural providers. The committee recommended consolidating the definition of rural to one definition. In the past, "rural" meant something different for hospitals versus health clinics. The committee also recommended focusing on investing in best practices, as well as providing more information to rural providers about the more than 200 HHS programs that affect rural communities and their health care entities.

What Needs to Be Done

We've made great strides in addressing the burdens dealt with by hospitals and caregivers every day. But by continuing the collaborative working partnership between hospitals, HHS and Congress, we can make even bigger strides to reduce the red-tape burden on caregivers and strengthen our ability to continue providing the world class medical care that is the hallmark of our health care system.

Specifically, we would urge you and your colleagues to examine additional areas for reform.

- The Medicare Cost Report—This is a relic of a previous cost-based payment system, which was used prior to the current prospective payment system. This should be evaluated and overhauled to reduce its size and complexity, and modify or eliminate the arcane Medicare-specific cost accounting principles.
- EMTALA—We believe that EMTALA provisions should not apply to inpatients. Congress enacted EMTALA to ensure that people have access to emergency services regardless of their ability to pay. Once a person is admitted as an inpatient, the hospital has taken responsibility for more than is required under EMTALA. At that point, the usual hospital-patient and doctor-patient relationships exist, creating duties of care for the hospital and physicians, and giving patients legal recourse if those duties aren't met. In addition, keeping all hospital staff current on EMTALA—not just the statute and formal requirements, but the continually evolving informal guidance—takes additional time away from providing direct patient care.
- Allow providers direct access to courts to challenge decisions—Unlike other federal agencies, Medicare program policy decisions made by the Secretary are insulated from judicial review. Health care providers are required to exhaust all administrative processes and remedies before they can file suit against HHS. However, there is effectively no such process to exhaust on questions about whether the Secretary has exceeded his authority or failed in his duty.

  Under Shalala v. Illinois Council on Long-Term Care, 120 S. Ct. 1084 (2000), the Supreme Court held that all matters arising under the Medicare Act must be channeled through the Secretary and that court review was available only following the administrative process. This continues to permit HHS to rebuff any and all lawsuits against the Secretary for failing to channel a claim, even when there is no administrative process available. This means that the Secretary can act outside the scope of his authority, without following required procedures and be insulated from judicial review—unlike other federal agencies.

The only time an administrative process is available to hospitals is if they are terminated from the program. Consequently, as currently interpreted, the only means for hospitals to challenge an unlawful action by the Secretary is to fail to follow or "violate" the rules in order to be terminated from the program.

- Simplify data collection process—Currently OASIS and MDS use very similar data collection tools, but they are unable to communicate with one another and share data.
- Establish Guiding Principles for Regulation—Regulation is essential to protecting patients and building public trust and confidence in the system. But unnecessary, poorly targeted or poorly implemented regulations may be of little benefit to the public, often frustrates health care providers and the patients they serve, and can even interfere with appropriate care delivery. We

would suggest that the following be used as guiding principles for the promulgation of health care regulation:

- The need to regulate behavior and the underlying objective of a regulation must be clear, unambiguous and well documented. For hospitals, regulations should be used to protect patients from harm, ensure that quality and other care and safety standards are met, inform the public about their care, prevent fraud and abuse, control expenditures under government programs and ensure fair functioning of the market for competing providers.
- Regulation should facilitate channels of communication between regulators and providers, and accountability of providers to their patients and communities.
- Regulation should be cost effective. It should be linked to specific objectives and regularly assessed as to whether it achieves its objectives; should be based on sound scientific, technical, economic and other relevant information; minimize the cost of compliance assessment for both the regulated and regulators; and embody the greatest degree of simplicity and understandability possible.
- Regulations should establish a safe haven for innovation and encourage the pursuit of excellence through best practices.
- Regulations should be applied prospectively and their implementation appropriately staged to avoid disrupting patient care activities, unnecessary costs and overwhelming administrative functions and information systems.
- Interpretive guidance and CMS manuals should be kept up to date and harmonized with underlying regulations. All too often, the guidance and manuals are out of date and thus present conflicting rules for providers and patients.

Conclusion

Our first priority is to provide high quality care to our patients. While some regulations contribute to this goal, others drain away much needed resources, placing a strain on our hospitals and the men and women who work there.

We believe the health care field should be regulated—but in a common sense fashion that allows health care providers to do what they've been trained to do—care for the ill and injured of our communities.

Thank you for your time today. On behalf of the American Hospital Association and its members, we look forward to working with you and your colleagues further to provide relief from overly burdensome regulations.

Chairman JOHNSON. Thank you. Dr. Hill.

STATEMENT OF J. EDWARD HILL, M.D., CHAIRMAN, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION

Dr. HILL. Good afternoon. My name is Edward Hill, and I am Chair of the Board of Trustees of the American Medical Association. I am a practicing family doctor in Tupelo, Mississippi. Of course I am very pleased to be here.

I would like to thank Chairman Johnson and Ranking Member Stark for all of their work on regulatory reform in the Medicare program and for advancing the Medicare Regulatory and Contracting Reform Act, MRCRA, last year. The AMA was a strong supporter of that bill, and we believe that physicians still need the regulatory relief in the MRCRA bill.

The AMA was pleased to participate in the HHS Regulatory Reform task force headed by Dr. Wood also. We were very supportive of his recommendations, especially those on EMTALA and Evaluation and Management (E&M) documentation guidelines.

We also appreciated the efforts of the Physicians Regulatory Initiative Team (PRIT). They have led to important clarifications in CMS policy. For example, in my practice, preoperative visits had been routinely denied prior to the PRIT action. However, the AMA

believes that regulatory reform as outlined in MRCRA is still needed as many Medicare carriers have not altered their overpayment audit practices relating to extrapolation, to appeals, and to repayment schedules.

The AMA believes that the need to educate physicians has not diminished since the House last considered MRCRA. The GAO highlighted this problem in 2002. It found that contractors gave inaccurate or incomplete answers 85 percent of the time, and these were answers to frequently asked questions that were posted on the carrier's Web site.

The AMA was pleased to learn about the new CMS carrier manual changes on physician education. The new standards for Web pages and frequently asked questions will be very useful. We urge CMS and the Subcommittee to closely monitor whether these changes are actually occurring. The CMS should also incorporate these education requirements in its annual evaluation of carriers. However, even with these changes, physicians still cannot call their carriers with billing or coding questions and receive clear, accurate, written answers nor can physicians rely on live telephone conversations or enhanced carrier Web sites when they are audited. Physicians can face punitive overpayment demands even when they follow carriers' advice.

The MRCRA would allow physicians to rely on carriers' advice if they were audited. Physicians still need the extrapolation reforms in MRCRA. The AMA believes that these reforms have not occurred uniformly at the carrier level.

For example, carriers still use extrapolation to magnify alleged overpayments. Problems found in a very small sample of claims are extrapolated to all similar claims over a 1- to 2-year period. This is not statistically valid, and it is often the first indication that a physician has of a billing problem. The MRCRA would have allowed CMS contractors to use extrapolation only when there was a high error rate or when documented education efforts had failed.

Administrator Scully testified last year that physicians and providers should have the same rights as taxpayers when they are audited by the Internal Revenue Service. That is, as long as interest accrues, taxpayers do not repay alleged overpayments that are on appeal. Unfortunately, at this point, physicians do not have these rights. Currently physicians must remit alleged overpayments within 30 days, even if they are appealing an overpayment audit finding.

According to HHS statistics, it takes 3 years to get to the highest administrative appeal level. The MRCRA would have required payment of alleged overpayments after the first level of appeal. This was a solid compromise between repayment after all appeals are exhausted and the current situation where physicians must remit all alleged overpayments prior to appeal.

Finally, CMS has withdrawn proposed E&M documentation requirements. However, it is working with AMA and national medical specialty organizations to develop clinical examples and standards for new guidelines. As this progresses, any new guideline must be tested to ensure their accuracy prior to implementation. The MRCRA is needed to ensure that the guidelines increase clin-

ical pertinent documentation and decrease irrelevant documentation.

The MRCRA would also establish pilot projects to test the viability of the guidelines. It would ensure that a sufficient number of physicians were participating in the pilot projects by prohibiting audits that target those physicians.

So, we appreciate the Subcommittee's consideration of the AMA's concern, and we appreciate your work on a number of issues that have already improved patient access and quality of care. We very much value the Subcommittee's work on regulatory reform issues and CMS's efforts to improve physician education.

We believe, working together, we can ensure that physicians obtain more complete due process rights and billing and coding answers that can be relied upon. So, we thank you for your time and particularly the time that the Subcommittee staff has devoted to this issue. Thank you.

[The prepared statement of Dr. Hill follows:]

Statement of J. Edward Hill, M.D., Chairman, Board of Trustees, American Medical Association

The American Medical Association (AMA) would like to thank the Ways and Means Health Subcommittee, Chairwoman Johnson, and Ranking Member Stark for holding this hearing on the continuing need for regulatory reform in the Medicare program and the impact that certain burdensome regulations are having on physician practices.

Background

The AMA is very appreciative of last year's findings by the Secretary of Health and Human Services (HHS) Regulatory Reform Task Force. We were pleased to participate in the Task Force's efforts, and we were very supportive of its recommendations. In particular, HHS adoption of the Task Force recommendations on EMTALA, evaluation and management documentation guidelines, advance beneficiary notices and communications with physicians and providers would significantly decrease the regulatory burdens that physicians currently face. Even before the Task Force report was finalized, the Centers for Medicare and Medicaid Services (CMS) initiated several changes in the area of simultaneous and continuous call for emergency care that the AMA had strongly advocated, and we are awaiting publication of final regulations to determine the extent to which EMTALA regulatory burdens will be improved.

The AMA has also been pleased with several CMS-generated reforms that have recently occurred. As a result of the Physicians Regulatory Initiative Team (PRIT), CMS has lengthened the period of time before prescriptions for diabetes tests strips must be renewed from six months to one year. In addition, successful PRIT efforts resulted in CMS clarifying its policies so carriers now know that preoperative physician visits are covered under Medicare. These changes, while seemingly minor, are decreasing the regulatory red tape for significant numbers of chronically or acutely ill patients and for their physicians.

At the same time, other significant areas remain where the AMA believes that regulatory reform is still needed. In particular, the AMA continues to hear from physicians regarding onerous audits and overpayment demands. Many Medicare carriers simply have not altered their overpayment audit practices related to extrapolation, appeals, and repayments of alleged overpayments. For example, one nine-person pathology practice continues to be subject to repeated audits of the same surgical pathology service, even though the carrier has never identified any billing errors or demanded overpayments. This practice is considering discontinuing the provision of surgical pathology consultation services to the hospital's Medicare patients, simply because of the time, expense and hassle factor associated with these audits. For the most recent of these audits, the carrier demanded charts on 200 patients.

The AMA believes that enactment of the Medicare regulatory reform bill that the House passed in both sessions of the 107th Congress would impose uniform stand-

ards on carriers. Such standards would ensure that physicians maintain due process rights during overpayment audits.

The AMA was a strong supporter of the "Medicare Regulatory Contracting Reform Act," (MRCRA), and we very much appreciate the work of this Subcommittee and in particular Chairwoman Johnson's and Ranking Member Stark's efforts in advancing MRCRA. Indeed, the House approved the MRCRA provisions twice, and we strongly urge it to do so again this year either separately or as part of overall Medicare reform.

Education

The AMA believes that a pressing need to educate physicians exists which has not decreased since the House of Representatives last considered MRCRA. This education deficiency was detailed in the February 2002 General Accounting Office (GAO) report "Medicare: Communications with Physicians Can Be Improved," which found that when GAO called contractors (callers identified themselves as calling from the GAO), contractor employees gave inaccurate or incomplete answers to questions 85% of the time. GAO further reported that these questions had been previously identified by the contractors as "frequently asked questions" and posted on the carriers' Web sites.

In its report to this Committee a year ago, the GAO also noted that CMS defined an accurate response as being any response that was not inaccurate. In other words, as long as the carrier did not provide the wrong information to the questioner, the response was considered "accurate," even if the carrier did not provide necessary and complete information to allow correct billing. To exacerbate matters, the carriers would not give physicians written answers to their billing and coding questions, even though answers given via the telephone were often incorrect. The GAO report stated:

> Information given to physicians by carriers is often difficult to use, out of date, inaccurate, and incomplete. Medicare bulletins that carriers use as the primary means of communicating with physicians are often poorly organized and contain dense legal language . . . Although CMS is tasked with assuring that carriers are responsive to physicians, the agency has established few standards for carriers to meet in their physician communications activities. CMS provides little technical assistance to help carriers develop effective communication strategies.

CMS has taken certain steps to improve its communications with physicians. In this regard, the AMA was very pleased to learn that CMS issued carrier manual changes on January 24, 2003, on Provider/Supplier Education and Training. These strong measures have the potential to significantly improve carriers' communications with physicians. The carrier manual standards related to web page content and frequently asked questions are very strong and will be helpful to physicians seeking information. However, the AMA urges CMS and the Subcommittee to monitor closely the carriers' abilities to effectively complete these new functions without commensurate funding increases. In addition, the AMA strongly urges CMS to incorporate implementation of these education requirements in its annual evaluation of carrier performance.

Despite the improvements made by the carrier manual, physicians are still not able to call their carriers with billing or coding questions and be assured that they will receive clear, concise and accurate answers, or written answers. Nor does it allow them to rely on answers generated by live telephone conversations or through the enhanced carrier Web sites when they are audited. Physicians have expressed concern that they face punitive overpayment demands even when they adhere to advice given to them by their carriers, and that carrier personnel are unwilling to provide their names so that physicians can contact them to follow-up on information that has been provided. MRCRA would have allowed this type of reliance, which the AMA believes is essential for physicians seeking to treat Medicare patients.

Extrapolation

Physicians are still in need of the extrapolation reforms that MRCRA offered, and the AMA believes that these reforms have not occurred uniformly at the carrier level. Although GAO reported in May 2002 on a study of three carriers' auditing practices, and found that they had decreased dramatically their use of extrapolation due to CMS' Progressive Corrective Action Plan, this reduction has not been uniform, permanent, nor has it occurred at the consent settlement level. In consent settlements, carriers continue to use "extrapolation" to magnify the alleged overpayments found in a very small probe sample of claims to all of these type of claims

submitted by a physician or provider of services over a one-to-two year period. This technique lacks any semblance of statistical validity, but it can lead to overpayment demands in the hundreds of thousands of dollars. Even more egregious, the letter demanding repayment of these huge sums is often the first indication physicians have that there are problems with their billing practices. MRCRA would have remedied this situation by allowing CMS contractors to use extrapolation to project an overpayment only in instances where there was a high error rate or where documented education efforts had failed. The AMA was gratified that the House recognized that carriers' use of extrapolation was a serious problem, and we urge the Subcommittee to address these extrapolation issues through legislation.

Repayment Plans

CMS has not instituted changes that would establish uniform repayment plans for physicians. Currently, carriers require complete repayment of alleged overpayments by physicians within 30 days unless physicians demonstrate that immediate repayment would create financial hardship. Demonstrating hardship often involves showing that the practice has no access to the money and cannot borrow it. Anyone who has applied for a loan is likely to understand how difficult it can be to complete an application, assemble the requisite documentation, and attempt to get a "yes" or "no" answer from the bank within 30 days.

Carrier overpayment demands for almost immediate repayment have harmed certain physician practices' viability, resulting in them being unable to provide an adequate level of service to their patients. The AMA urges the Subcommittee to consider provisions to ensure that if the overpayment represents more than ten percent of the physician's Medicare revenue, then the physician would be able to repay the program over a three-year period. When alleged overpayments represent a high proportion of practice revenues, immediate repayment demands can pose a major economic hardship to the practice.

Evaluation and Management (E&M) Documentation Guidelines

Although CMS has withdrawn proposed documentation requirements, it is currently working with the AMA and national medical specialty organizations to develop new clinical examples and standards for new guidelines. As this process progresses, any new proposed guidelines must be tested to ensure their accuracy prior to national implementation. The AMA believes that legislation like MRCRA is needed to establish that the guidelines must meet important objectives, such as increasing clinically pertinent documentation and decreasing irrelevant documentation, and to establish pilot projects to test the viability of any proposed evaluation and management documentation guidelines. In addition, MRCRA would have also ensured that a sufficient number of physicians participated in the pilot projects by prohibiting audits for documentation that occurred as part of the pilot project.

Consent Settlements—Due Process

Carriers continue to employ the consent settlement process which does not permit physicians to contest the validity of a probe sample without being forced to submit to a statistically valid random sample (SVRS) of 200–400 claims, which is very disruptive to a physician practice. CMS has indicated that 90 percent of settlement offers are accepted. The AMA believes that this high acceptance rate is not a true measure of "consent," but instead is evidence that the only other options available to physicians are even more onerous than repaying the large sums that are often demanded. Physicians should not be forced to agree to an SVRS in order to maintain their appeal rights. Physicians should be permitted to submit additional justifications of billing claims and to engage in constructive discussions with their carriers to argue that an initial overpayment allegation is incorrect. If the physician decides not to submit justifications for a claim, then he or she would either have to pay the alleged projected overpayment or agree to an SVRS. This ability to justify the claim is an essential due process right that should be afforded to physicians—especially in light of the probe sample's use in determining projected overpayments.

Repayment During Appeals

Currently, physicians must remit alleged overpayments in full within 30 days even if they are in the process of appealing an overpayment audit finding. The AMA strongly supported the Subcommittee's efforts to permit physicians, providers of services, and suppliers to repay an alleged overpayment after a reconsideration has occurred. Administrative law judge (ALJ) decisions took an average of 389 days in the first quarter of 2001 and departmental appeals board decisions (DAB) took an

average of 661 days to complete. If the physician, provider of services, or supplier is successful at the DAB level, it is likely that three years have elapsed since the physician's payment of an alleged overpayment to the CMS contractor. MRCRA was a solid compromise between not requiring repayment until all appeals were exhausted and the current untenable situation where physicians must remit all overpayments prior to appealing a finding.

CMS Administrator Scully testified last year that physicians, providers of services, and suppliers should have the same rights that taxpayers have when they are audited by the IRS; that is, as long as interest accrues, taxpayers do not have to repay alleged overpayments while administrative appeals are pending. Unfortunately, at this point, physicians do not have the same rights as taxpayers when they are faced with an IRS fine, but are forced to repay alleged overpayments within 30 days.

Provider Enrollment

Under current law, physicians, providers of services, and suppliers cannot appeal a contractor's decision to deny or revoke a Medicare provider number. For most health care practitioners, the denial or revocation of a provider number is an extremely serious occurrence that prohibits them from submitting any claims for reimbursement to the Medicare program. Physicians can request that the carrier reconsider their application, and then can request a hearing by an entity or person appointed by the Secretary of the Department of Health and Human Services, but beyond this level, there is no recourse.

This issue may be further exacerbated by the new requirement that CMS has instituted (without a public notice and comment period) that contractors must revalidate enrollment information every three years. As contractors have been given neither uniform standards nor funding to conduct these revalidations, this could lead to an avalanche of experienced physicians and providers being suddenly rejected from the Medicare program.

Additional Provisions

The Secretary has not, at this point, established standards for random prepayment audits, as would have been required under MRCRA. MRCRA's proposed standardization of random prepayment audits would have ensured that contractors no longer have unlimited discretion as to the circumstances that would trigger random prepayment audits. Under the bill, prepayment audits would have had defined endpoints, instead of placing an enormous strain on practices' cash flow as claims are held up for payment while audits continue. Without the legislation, there are no existing procedures to remove physicians from prepayment review once their billing practices are sufficiently compliant with Medicare policies.

The AMA also appreciates the additional resources that MRCRA would have directed towards administrative law judges. This funding would have increased the number of administrative law judges and improved education and training opportunities for the judges and their staffs. None of this has occurred.

Within the context of contractor reform, we are concerned that CMS is reducing its reliance on the services of carrier medical directors. In particular, the Arkansas carrier has decided that the Louisiana medical carrier will serve not only as the medical director for Louisiana, but also for Oklahoma and New Mexico (aforementioned states are under the Arkansas carrier's purview). The Arkansas carrier's medical director will be serving in this capacity for both Arkansas and Missouri.

The AMA believes that each state should have the benefit of a state-specific, full-time medical director. As we stated in a letter co-signed by over 130 national and state medical organizations, "A single carrier medical director (CMD) serving multiple states undermines the effectiveness of the CMD . . . and CMDs provide unique access to the local physician community that is difficult, if not impossible, to replace by contractor non-physician personnel."

We appreciate the Subcommittee's consideration of the AMA's concerns. We very much value the Subcommittee's work on regulatory reform issues and the efforts that CMS has undertaken to improve physician education. However, the AMA believes that we can work together to ensure that physicians obtain more complete due process rights and billing and coding answers that can be relied upon by the physician. We thank you for the time that your Subcommittee, and particularly, the Subcommittee staff has devoted to this issue.

Chairman JOHNSON. Thank you very much. Ms. Wolf.

STATEMENT OF JANET B. WOLF, PRESIDENT, MUNSON HOME HEALTH, TRAVERSE CITY, MICHIGAN, AND PAST PRESIDENT, BOARD OF DIRECTORS, MICHIGAN HOME HEALTH ASSOCIATION, OKEMOS, MICHIGAN, ON BEHALF OF THE NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE

Ms. WOLF. Thank you, Madam Chair, Representative Stark, and Subcommittee Members for inviting me to testify on the value of Medicare regulatory reform to beneficiaries and providers. My name is Janet Wolf. I am president of Munson Home Health, a not-for-profit subsidiary of Munson Health Care, a northern Michigan health system based in Traverse City. Munson Home Health provides services to 32 rural counties.

Madam Chair and Members of the Subcommittee, you are to be commended for developing H.R. 3391 that unanimously passed the House. Unfortunately, it did not become law. Once again, you are taking a leadership role in redrafting and advancing new legislation to simplify the highly regulated and often burdensome Medicare program.

As a home care provider, I join the Munson Home Health Association (MHHA) and the National Association for Home Care (NAHC) in supporting the provisions of your bill to prohibit retroactive application of substantive changes in regulations or policies, extend protection against compliance actions related to changes until 30 days after the change is issued, protect providers against sanction in cases where they have followed written guidance from a Medicare contractor, improve Medicare contractor compliance, improve provider education, and establish a provider ombudsman.

Regarding Medicare appeal reform, NAHC strongly supports many of the modifications to the Medicare appeals process as set out in BIPA. The NAHC submitted extensive comments in response to that proposal. For the Committee's reference, a copy of those comments is attached.

Recommendations include preserving the independence of the ALJs, ensuring a speedy appeal process, ensuring that recovery of overpayments is not initiated before the conclusion of the first step in the appeal process.

In reference to recovery of overpayments, we would like to recommend that the Subcommittee protect providers from retroactive overpayment recovery when the overpayment is caused by administrative action more than 1 year previous, and include consideration for extended repayments under hardship criteria standards, such as no greater than 10 percent of the Medicare revenue per year, and permit minor errors or omissions to be corrected without formal appeals process.

Concerning the issue of flexibility in applying the Medicare conditions of participation (COPs), NACH recommends the Subcommittee consider three potential approaches to this overregulation:

One, amend Medicare law to clearly provide that the COPs apply only to Medicare patients.

Two, instruct the Secretary of HHS to take steps to tailor the COPs to the various type of patients served by a home health agency distinguishing the Medicare-type patients from those receiving just personal care or private duty shift nursing service.

Third, support enactment of a provision that would allow a home health agency to operate with several internal divisions, with Medicare certification applying to distinctly designated divisions, similar to the process used in nursing facilities.

The broad-based application of the Medicare COPs to all patients creates extra cost, bureaucracy, and paperwork burdens and ultimately we all pay for these costs.

Madam Chair and Subcommittee Members, with regards to OASIS, over the last couple of years, NACH has been actively engaged in pursuing the streamlining and reduction of the OASIS instrument through the submission of testimony and recommendations to this Subcommittee, as well as working with the HHS Secretary's Advisory Committee on Regulatory Reform and with CMS Administrator Tom Scully.

Most of this effort was triggered by this Subcommittee's encouragement to CMS. I refer you to attachment 2 for more details.

In December 2002, several of these changes were implemented by CMS, including elimination of 2 of the OASIS collection time points and 17 data items. This is a good beginning. We have listed 15 of the Secretary's Advisory Committee recommendations in the testimony. Many of these recommendations, however, have not been implemented.

Madam Chair, we support these recommendations and ask that the Subcommittee intervene in this process and press for full and immediate implementation. While there is industry-wide support for an outcome-based assessment, home care agencies have consistently requested that CMS eliminate the nonessential and redundant OASIS components. OASIS must be quickly streamlined to reduce agency costs and improve staff satisfaction.

The OASIS continues to be the number one reason for nurses leaving the home health setting and the only reason nurses leave my agency. This is also a major problem for patients.

The NAHC recommends that the Subcommittee also instruct the Secretary to implement nine additional items for OASIS simplification. You can see these in your testimony, and I welcome questions on why any of them are important.

Finally regarding hospice regulatory reform, we urge you to direct CMS to move forward and publish the conditions of participation through a notice of proposed rulemaking. The hospice conditions have not been updated since 1983.

In closing, I cannot thank you enough, Madam Chair, for your longstanding efforts on behalf of our Nation's home health providers and the patients and families they serve.

This concludes my formal remarks, but I would be happy to answer any questions.

[The prepared statement of Ms. Wolf follows:]

Statement of Janet B. Wolf, President, Munson Home Health, Traverse City, Michigan, and Past President, Board of Directors, Michigan Home Health Association, Okemos, Michigan, on behalf of the National Association for Home Care & Hospice

Thank you, Madame Chairman, Representative Stark, and Subcommittee members, for inviting me to present testimony on ways to bring regulatory relief to beneficiaries and providers, and specifically to discuss the many benefits that would result from enactment of Medicare regulatory reform legislation. My name is Janet Wolf. I am President of Munson Home Health, a not-for-profit subsidiary of Munson

Healthcare, a northern Michigan health system based in Traverse City. Munson Home Health provides services in 32 rural (non-MSA) counties. I am also the Past President of the Board of Directors of the Michigan Home Health Association (MHHA), a voice for home care in Michigan, and a member of the National Association for Home Care and Hospice (NAHC).

NAHC is the largest national organization representing home health care providers, hospices, and home care aide organizations. Among the nearly 6,000 organizations NAHC represents are every type of home care agency, including nonprofit agencies like the VNA, for-profit chains, public and hospital-based agencies, and free-standing agencies. MHHA represents some 300 providers including Medicare-certified home health agencies, hospice agencies, private-duty provider organizations, home medical equipment and pharmacy infusion providers in Michigan.

In September 2001, NAHC had the honor of being called before this panel to provide testimony on a number of the regulations and policies that impact a provider's ability to deliver high-quality patient care in an efficient manner. We are pleased to be back here today to personally extend our most sincere thanks for the many efforts that you, members of this Subcommittee, your staff, and others have made to ease burdens on home care and other providers.

Madame Chairman, you and all of the members of the Subcommittee particularly, are to be commended for developing HR 3391, the "Medicare Regulatory and Contracting Reform Act of 2001." In 2001, this bipartisan legislation unanimously passed the House 408–0. Unfortunately, there was no action by the Senate to conference the differences between their bill and your unified House bill—HR 3391. We are glad that you are once again taking a leadership role in redrafting and advancing new legislation to simplify the highly regulated and often burdensome Medicare program. Medicare regulatory reform legislation will go a long way toward easing the impact of some of the most troublesome policies of the Medicare program. In reviewing HR 3391, you have included a number of provisions that address specific problems that hospices and home health agencies have struggled with in recent years, including:

New Requirements for Regulatory and Policy Issuances

Among the changes that would have been enacted as part of HR 3391, you have included several provisions related to regulatory or policy issuances that will be of tremendous help to providers. First, the legislation prohibits any provision published in a final regulation that is not a logical outgrowth of the proposed regulation from taking effect until after appropriate opportunity for public comment. Additionally, your bill generally prohibits retroactive application of substantive changes in regulations or other policies, and extends protection against compliance actions relative to the change until 30 days after issuance of the change. Home care has faced great difficulties in the past with policy issued with retroactive impact, such as the revision in standards for allowable branch offices. The bill should prevent this in the future.

The bill also protects providers against sanction in cases where they have followed written guidance from one of Medicare's contractors. Home health agencies have followed written guidance from intermediaries on cost reporting only to find the intermediary later rejecting its own approval. This has led to unfounded allegations of overpayments. NAHC is appreciative of your actions with respect to this particular provision in clarifying what constitutes a sanction. We are pleased that providers shall not be subject to any sanction, including any penalty or requirement for repayment of any amount if the provider received and relied on written guidance from the intermediary.

Contractor Accountability

NAHC applauds your efforts as part of HR 3391 to improve Medicare contractor compliance and accountability through development of specific performance measures. We also believe that the emphasis you have placed on provider education is a sound foundation for improved provider relations with the contractors and greater understanding of the Medicare program. Of particular note is the bill's provision for technical assistance and program information to providers as one of the contractors' key functions. The availability of program information is so vital to the ability of providers to operate in compliance with the program that NAHC recommends inclusion of a similar provision applicable to Medicare's contractors for survey and certification, the state survey offices. An educational role for state survey offices is a key way to secure quality of care for patients.

Section 302 of HR 3391 establishes a Small Provider Technical Assistance Demonstration Program. We believe that this is an excellent approach for evaluating billing and other practices of small providers to ensure compliance with Medicare

law. As you know, Madame Chairman and members of the Subcommittee, the vast majority of home health agencies and hospices are small businesses that could greatly benefit from participation in such a demonstration. We support this effort wholeheartedly.

Medicare Provider Ombudsman

Your establishment, under Section 303, of a Medicare Provider Ombudsman is a concept that NAHC has long advocated, and is very much in keeping with the spirit of your efforts and those of others who are working to ease regulatory burdens.

Medicare Appeal Reform

NAHC strongly supports many of the modifications to the Medicare appeals process as set out in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and in Title IV of HR 3391. Currently, the Centers for Medicare and Medicaid Services (CMS) have issued proposed rules to implement the BIPA provisions. NAHC submitted extensive comments in response to that proposal. For the Committee's reference, a copy of these comments is attached (Attachment 1).

In considering further refinements on Medicare appeals, NAHC suggests that the Committee consider three goals in that reform. First, the independence of the administrative law judges (ALJ) that preside over fair hearings should be preserved. Of particular concern is the proposal by CMS to require ALJs to abide by informal policy guidelines unless the ALJ can explain why those guidelines should not be followed. These guidelines do not have the force and effect of law and should not be afforded presumptive validity. Second, it is crucial that the appeals process operate within reasonable and structured time deadlines as current delays may often mean that the appeals process survives longer than the patient or provider. Third, the Subcommittee should preserve the non-adversarial nature of the appeals process. CMS proposes to allow its contractors to act as parties in the appeals process with full rights to be represented by counsel, present evidence and argument, and pursue further appeals. In many of the administrative appeals, the cost of such action would outweigh the value of the matter in controversy.

Recommendations

1. Congress should ensure that the independence of ALJs is maintained.
2. Congress should ensure that there is a speedy appeals process.
3. Congress should prohibit the institution of an adversarial appeals process.

Recovery of Overpayments and Prepayment Review

In Section 405 of HR 3391, several protections were made available to providers of health services under Medicare in relation to the recovery of overpayments. NAHC strongly supported the efforts to establish these protections. In particular, the amendment that would prohibit any recoupment of an overpayment until after a decision had been rendered through the first step in the appeals process provided a reasonable mechanism to insulate providers of services from wrongful payment recoveries. Under the home health and hospice programs, many denied claims are reversed on appeal. By delaying any recoupment until after the close of the first appeals step, providers of services can avoid unnecessary financial jeopardy where there is an error in the overpayment determination.

The bill also appears to limit the postponement of the overpayment recovery to circumstances where the provider has initiated the appeal. While providers are afforded improved appeal rights under the pending CMS proposal, currently a provider does not have a direct appeal right and must proceed as the beneficiary's representative in order to have the dispute reviewed. For example, a claim denial based on an alleged failure to submit a document can only be appealed by the beneficiary even though the provider suffers the financial consequences. We would suggest that the language of this provision be modified to provide the pre-recovery protection in all instances where the issue in dispute is under appeal.

HR 3391 also established standards for the approval of an extended repayment plan on overpayments allowing for up to three years for repayment in cases of hardship and up to five years for circumstances involving an extreme hardship. Home health agencies are just now completing repayment of the significant amounts of money that the Medicare program considered an overpayment under the former reimbursement system known as the Interim Payment System (IPS). During that recovery action, it became apparent that even a 36-month repayment plan was too short a time if home health agencies were expected to continue access to care. Last year's legislative proposal would have helped home health agencies to secure further needed protection. NAHC encourages the Subcommittee to continue support for this necessary improvement in Medicare administration. At the same time, we strongly

recommend that the definition of "hardship" be amended. The bright line test for "hardship" to qualify for a repayment plan is set at 10 percent of the provider's Medicare income. While that standard may make it administratively simple to apply, it does not adequately address the financial jeopardy faced by home health agencies and hospices with overpayment obligations at less than 10 percent. With most of the cost of delivery of home health and hospice services related to labor, immediate repayment of an overpayment at a level less than 10 percent would have significant impact on cash flow and wage payment obligations. We would urge that some discretionary authority be extended so that special circumstances are considered as exceptions to that rule.

Under the Subcommittee's bill, Medicare contractors would be permitted to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing. Madame Chairman, the duplication of records can be costly and time consuming. It is our hope that this particular provision was designed to encourage contractors to limit their requests to what is absolutely necessary, rather than to affirm some of the contractors' current practices.

Use of statistical sampling by Medicare's contractors has been a significant problem for home health agencies at times, and we applaud your efforts to limit its use only to cases in which there is a sustained or high level of payment error or where documented educational interventions have failed to correct the payment error. This should ensure that sampling is used only in appropriate circumstances.

We would urge the Subcommittee to include an additional provision in its regulatory reform proposal. That provision would provide protection to health care providers where the "overpayment" relates to an error in the administration of the Medicare benefits by the Medicare program itself. Currently, home health agencies are facing a liability of an unknown amount as a result of Medicare's inability to appropriately process a Medicare home health PPS claim. Specifically, Medicare home health PPS rules require a payment adjustment when a patient is admitted to another home health agency or readmitted to the same home health agency within the 60-day episode period following a discharge. The payment adjustment involves a "partial episode payment" adjustment for the first episode of care within the 60-day period. CMS determined over a year ago that its system failed to make these payment adjustments from the beginning of home health PPS, October 1, 2000, for many partial episodes. Home health agencies were unable to account for many of these adjustments since they were unable to track an individual's post discharge home health services provided by a different agency. Furthermore, even when providers became aware of the need for adjustments, they were unable to submit corrected claims due to system problems. CMS now intends to retroactively make significant payment adjustments.

NAHC recommends that the Subcommittee include legislation that would limit the ability of CMS to institute retroactive payment adjustments on any claims from more than one year previous. Providers cannot maintain financial integrity by carrying a financial liability of an unknown amount from one fiscal year into another. Equities dictate that providers of services should be held harmless for payment process errors of CMS that extend over a long period of time.

Recommendations

1. Congress should enact overpayment recovery process protections as set out in HR 3391 with modification to address providers with overpayments equal to less than 10 percent of total Medicare annual revenue.
2. Congress should enact a provision to protect providers of services from retroactive payment recovery when the overpayment is caused by an error of the Medicare administration and the error involves an action from more than one year previous.

Ability to Correct Minor Errors and Omissions on Claims

Section 407 of HR 3391 establishes a process for correction of minor errors and omissions on claims without pursuing an appeals process. The vast majority of home health and hospice claims that are denied are rejected because they do not meet one or more of the technical requirements set out by the Medicare program. Under current practice, if an agency fails to meet a technical requirement in developing and filing claims—examples of which are failure to record the verbal order date on the plan of care, secure physicians' signatures on all verbal orders prior to billing (including minor treatment changes), or date the receipt of signed orders if the physician has not dated his or her signature—the claim is denied and the agency's only recourse is to undergo a costly and lengthy appeals process. This can delay payment to the agency for up to a year and a half, and unnecessarily burden providers and

intermediaries. Your legislation would address this long-standing problem by establishing a process under which health care providers would be given an opportunity to correct these minor errors or omissions without having to initiate an appeal. We consider this change in the law as a significant advance for providers, patients, and the Medicare program that will achieve great savings while providing timely Medicare payment for necessary care.

Provide Flexibility in the Application of Medicare Conditions of Participation to Non-Medicare Patients

CMS, and its predecessor, the Health Care Financing Administration, has long held to the position that the Conditions of Participation for Medicare home health agencies should apply equally to all patients served by the home health agency regardless of payor source or the nature of services provided. This position has failed to address the wide variation in home care services provided to individuals served by a home health agency. The range of services may begin with personal care and homemaker services and extend to high tech infusion therapy and private duty nursing for technologically dependent patients. The Medicare Conditions of Participation are designed around the concepts within the Medicare home health benefit that focus on part-time or intermittent services for patients requiring skilled care while confined to the home.

NAHC recommends that the Subcommittee consider three potential approaches to this over-regulation.

1. Amend Medicare law to clearly provide that the Conditions of Participation apply only to Medicare patients. It should be noted that Medicaid home health services must be provided by a provider that meets the Conditions of Participation under Medicare.
2. Instruct the Secretary of HHS to take steps to tailor the Conditions of Participation to the various types of patients served by a home health agency distinguishing the Medicare-type patient from those patients receiving personal care only or private-duty-shift nursing services.
3. Support the enactment of a provision that would allow a home health agency to operate with several internal divisions with Medicare certification applying to distinctly designated divisions. This approach would mirror that allowed for nursing facilities where distinct part Medicare certification is permitted. Currently, CMS allows for a home care organization to operate with separate home care entities if such elements as separate incorporation, separate staff, and separate consumer identity are established. These separations should be unnecessary.

The broad-based application of Medicare Conditions of Participation to all patients of a home care organization creates needless cost, administrative bureaucracy, and unjustifiable paperwork burdens. Ultimately, these costs are absorbed by individual patients, Medicare, and non-Medicare payors of service.

The Outcome and Assessment Information Set (OASIS)

Over the last couple of years, NAHC has been actively engaged in pursuing the streamlining and reduction of the OASIS instrument through the submission of testimony and recommendations to this Subcommittee, as well as working with the Department of Health and Human Services' Secretary's Advisory Committee on Regulatory Reform and with CMS Administrator Tom Scully (Attachment 2). Much of this effort was triggered by this Subcommittee's encouragements to CMS. I am pleased to report that the Secretary's Advisory Committee has recently submitted recommendations to not only reduce regulatory burdens on home health and hospice providers but has also provided recommendations to streamline and modernize OASIS. The following recommendations were adopted by the Secretary's Advisory Committee.

1. Expand the time for completion of the OASIS instrument, from 5 days to 7 days. **Has not been implemented by CMS.**
2. Change the lock-in time for the OASIS instrument, from 7 days to 14 days. **Has not been implemented by CMS.**
3. Delete elements that are duplicative or not used for payment, outcome, quality management, or survey purposes. CMS should particularly scrutinize data elements, MO190, MO340, MO640-680, and MO780. **Has been partially implemented by CMS.**
4. Eliminate separate forms for significant change in condition when it occurs in the five-day window of the follow up assessment. **Has not been implemented by CMS.**

5. Eliminate OASIS encounters that are not used for payment, outcome quality management, or survey purposes. **Has been partially implemented by CMS.**
6. Create the option to use one form for all situations of care or change in status. **Has not been implemented by CMS.**
7. Share OASIS risk-adjustment methodology with all users. Make the information available on the CMS website. **Has not been implemented by CMS.**
8. Provide access to the studies on the validity of OASIS data, adverse event measurements, and OASIS quality and outcomes. **Has been implemented by CMS.**
9. Ensure data collection efforts facilitate the development of care plans. **Has not been implemented by CMS.**
10. Consider the impact of the Health Insurance Portability and Accountability Act (HIPAA) on home health agencies with respect to the timing of any changes to OASIS. **Will require ongoing oversight by CMS.**
11. Adopt a continuous quality improvement process to keep OASIS current with medical practice and changing delivery systems. CMS has organized a 3-year technical expert panel for this purpose.
12. Establish a scientific and technical advisory panel to guide OASIS use (measure work-ups, interpretation of data quality, interpretation of results, quality reporting, and assessment of need for new measures). **CMS has selected members to serve on the technical advisory panel.**
13. Conduct field tests of new OASIS measures before they are put into use. **CMS has added one new OASIS measure for HIPAA compliance but it has not been tested.**
14. Clarify the definition of "significant change." Consider using re-hospitalization as a proxy for "significant change." **Has not been implemented by CMS.**
15. Conduct an independent evaluation of the cost-benefit of using the OASIS form. **Has not been implemented by CMS.**

As of December 2002, CMS implemented a few changes aimed at decreasing the burden of OASIS data collection. These changes included elimination of two OASIS collection time points and seventeen data items. Thirteen of the seventeen data items consist of demographic information which have been moved to a "tracking sheet" to be completed by agency office staff. NAHC sees these changes as an excellent first step in the OASIS streamlining process and will continue to work with CMS to promote adoption of additional refinements to reduce OASIS items that are unnecessary for quality outcomes or for payment purposes.

Madame Chairman, we also support the Secretary's Advisory Committee's recommendations and ask that the Subcommittee intervene in this process and press for full and immediate implementation. While there is industry-wide support for an outcome-based assessment, home care agencies have consistently requested that CMS eliminate the non-essential and redundant OASIS components and requirements. OASIS must be quickly streamlined to reduce agency costs, increase direct patient care time, and improve staff satisfaction. OASIS continues to be the number one reason for nurses leaving the home health setting.

NAHC also recommends that the Subcommittee instruct the Secretary to immediately implement the following additional items for OASIS simplification. These recommendations can be implemented by policy changes or incorporated into the soon-to-be-published Conditions of Participation.

1. Amend the Medicare Conditions of Participation for Home Health and eliminate the requirement to collect OASIS data for skilled non-Medicare patients and non-Medicaid patients because this data is not being submitted to the CMS data repository for outcome measures.
2. Instruct the Secretary of HHS to take steps to make OASIS electronic program specifications and the risk adjustment methodology available to the public.
3. Request that CMS lengthen the definition for "inpatient stay" from 24 hours to 72 hours.
4. Request that CMS move to expand the time for completion of the OASIS instrument from 5 days to 7-10 days.
5. Instruct CMS to change the lock-in time for the OASIS instrument from 7 days to 14 days.
6. Instruct CMS to widen the recertification window from 5 days to 7-10 days, allowing for greater flexibility for agency scheduling the OASIS assessment during a scheduled patient visit.

7. Instruct CMS to eliminate the SCIC assessments since they are not used for any outcome measurements and unfairly penalize providers when exclusively used for payment purposes.
8. Request that CMS only use the 23 payment questions along with an agency assessment form for all LUPA episodes, including one-time-only Medicare visits.
9. Eliminate the requirement that an RN must complete the SOC assessment in all instances where RN services are not the primary service ordered.

Hospice Regulatory Reform

Madame Chairman and members of the Subcommittee, the hospice conditions of participation have not been updated since 1983. In 1995, CMS began the process of drafting new language that would streamline the Conditions of Participation. We urge you to direct CMS to move forward and publish the Conditions of Participation through a Notice of Proposed Rulemaking. Furthermore, we would also request that you consider a couple of regulatory changes that would help to simplify the Medicare hospice program. We are supportive of the provision within Title VIII Subtitle E—Miscellaneous Provisions, Section 846 of HR 4954, the "Medicare Modernization and Prescription Drug Act of 2002," which authorizes the use of arrangements with other hospice programs to provide core hospice services. This provision provides the flexibility needed to allow hospices to contract with other hospices during periods of high patient loads, staffing shortages, or temporary travel of a patient outside of the primary service area of their hospice. We suggest that you go one step further and allow hospices to make arrangements for highly-specialized clinical services. In the best interest of patient care, it is sometimes appropriate for hospices to utilize high technology treatments to achieve efficient and effective pain management. Some high-technology pain management interventions require highly specialized clinicians to administer such treatments. These incidents are infrequent and therefore it is impractical and prohibitively expensive for hospices to have such specialized caregivers on staff.

Conclusion

Madame Chairman and members of the Subcommittee, the issues addressed by your legislation may seem quite technical in nature, but they will make a tremendous difference in day-to-day operations of all types of providers. We in the home health and hospice world have sought a number of these solutions for many years and will work diligently for their enactment.

In closing, I cannot thank you enough, Madame Chairman, for your long-standing efforts on behalf of our nation's home health providers and the patients and families they serve.

This concludes my formal remarks but I would be happy to answer any questions that any members of the panel might have.

ATTACHMENT 1

NAHC COMMENTS TO CMS REGARDING CHANGES TO THE MEDICARE CLAIMS APPEAL PROCEDURES

January 14, 2003

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445
Washington, D.C. 20201

Re: CMS–4004–P, Changes to the Medicare Claims Appeal Procedures

To Whom It May Concern:

Thank you for the opportunity to provide comments to the Proposed Rule for Changes to the Medicare Appeals Process implementing Section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106–554. The National Association for Home Care & Hospice (NAHC) is the largest trade association in the country representing home health agencies, hospice programs and home medical equipment providers. Overall, the proposed changes to the appeal process are reasonably consistent with the BIPA requirements. In addition, the proposed rules address some longstanding confusion regarding Medicare appeals that results from the "bootstrapping" of many of the Social Security Administration appeals rules. While NAHC's general evaluation of the proposed rules is positive, these comments focus on areas of concern.

Security Administration appeals rules. While NAHC's general evaluation of the proposed rules is positive, these comments focus on areas of concern.

Qualified Independent Contractor

The changes enacted in BIPA require the creation of an entirely new entity in the Medicare claims review process, the "qualified independent contractor (QIC)." NAHC believes that it is necessary for the Centers for Medicare and Medicaid Services (CMS) to restrict the organizations eligible to qualify as a QIC. Specifically, NAHC believes that it is necessary to establish independence of the QIC from the fiscal intermediaries and carriers that issue initial determinations and redeterminations.

Recommendation

Prohibit fiscal intermediaries and carriers or parties related to intermediaries and carriers from becoming a QIC.

The Role of Contractors in ALJ and MAC Proceedings

CMS proposes to allow Medicare contractors to participate in Administrative Law Judge (ALJ) and Medicare Appeals Council (MAC) proceedings. Further, CMS proposes to allow the contractors to obtain "party" status at these stages of appeal and to have authority to obtain MAC review of any unfavorable ALJ decisions.

The proposal to provide participation and party status for Medicare contractors is a significant alteration of the appeals process, changing it from a non-adversarial proceeding that has existed from the beginning of the Medicare program into an adversarial process that is only likely to increase costs and heighten controversies.

Recommendation

Eliminate party and participation status for Medicare contractors, specify that the ALJ reviews are de novo, and allow ALJ and MAC consideration of contractor actions and reviews only for purposes of establishing appellate level jurisdiction. In the event that this recommendation is not accepted, specify that prevailing party attorneys' fees are available under the Equal Access to Justice Act in any appeals in which the contractor participates or achieves party status.

Limitation on New Evidence

The proposed rules significantly restrict the opportunity to offer additional and new evidence before an ALJ, requiring a full and early presentation of evidence at the QIC level. NAHC is aware that CMS has held to a longstanding belief that the high reversal rates on appeal are primarily due to the presentation of new evidence to the ALJs. However, the introduction of any new evidence at any step in the appeals process is designed to secure a fair and accurate determination. It is in the best interests of Medicare beneficiaries and providers of services to get that full and fair determination as soon as possible. As such, there is no indication that material evidence is withheld at any stage of the appeals process in hopes of improving chances of success months and months later down the line with succeeding appellate levels.

CMS should distinguish between the submission of new evidence that involves readily available clinical documentation from the provider of services directly implicated in the Medicare claim in dispute from other evidence such as expert opinion, clarifying treating physicians' opinion, and documentary evidence from providers of services not directly involved in the disputed claim. Most often, the new evidence submitted is done so to address issues raised by the preceding appellate level or to clarify matters that have been determined to be somewhat confusing.

Recommendation

Eliminate restriction on the submission of new evidence. Alternatively, apply the restriction on new evidence only to clinical documentation from the provider of services directly involved in the disputed claim.

The Role of LCDs, LMRPs, CMS Program Guidance, and Manual Instructions

CMS proposes to require that QICs "give deference" to local coverage determinations, local medical review policies, and CMS program guidance, including manual instruction. CMS proposes that QIC be required to follow these instructions "unless the appellant questions the policy and provides a reason that the QIC finds persua-

sive as to why the policy should not be followed." The effect of this standard is to provide informal policy positions of CMS and its contractors with the force and effect of law. It also requires appellants to directly challenge the application of these informal polices in circumstances where they may not be fully aware of the application of these policies to the issues in dispute nor have full access to these informal policies.

Recommendation

Eliminate requirement that QICs "give deference" to informal CMS and contractor policies. Alternatively, require that decisions issued by contractors specifically reference any informal policies applied in the decision making and provide information as to how the affected individual or provider can obtain copies of those policies. Further, require the QIC to inform the appellant of its intention to apply a particular informal policy to the issue in dispute and allow the individual an opportunity to challenge the application of that policy.

QIC Reviewer Competency

CMS proposes that QIC reviewers "have sufficient training and expertise in medical science and/or legal matters." 42 CFR § 405.968(c). This standard does not sufficiently set out a qualification that requires knowledge and experience in the area of healthcare that is in dispute. For example, training and expertise in medical science does not necessarily entail a knowledge of clinical necessity and medical appropriateness in a particular health setting, the ability to evaluate the terminal illness of a patient seeking hospice coverage, or the application of the "confined to home" standard under the Medicare home health benefit.

Recommendation

CMS revise the proposed rule to require sufficient knowledge and expertise in the area of health care in dispute.

Claim Reopening

CMS proposed to clarify rules and require that reopening of determinations at any level within the process be available only after a party's appeal rights have been exhausted or the time limit for appealing expired. In doing so, CMS indicates that clerical errors must be handled through the reopening process. As such, it appears that human and mechanical mistakes, such as clinical, mathematical, computational or inaccurate data entry must be addressed through the appeals process before any reopening action and correction can occur. Alternatively, reopenings for these corrections of minor errors and omissions would have to await the exhaustion or expiration of any appeal rights. Hopefully, this is a misreading of the proposed rule.

The reopening authority also improperly distinguishes between reopening requests from Medicare beneficiaries and providers of services and those reopening actions by the contractor on its own initiative. The same time frames and standards for reopening should apply to all parties and participants in the Medicare decision-making process. The reopening standards should provide for a reasonable level of finality with limited authority of the contractor to initiate reopening of its own decisions to address any perceived errors that have come through its own lack of diligence and effective claim review. If a contractor seeks to reopen a claim, it should be required to establish good cause for that reopening with a notice of intent to all affected parties and a right of appeal on the finding of good cause. For example, if a contractor reopens a series of claims two years after the original adjudication, the affected provider should be able to challenge that the contractor does not have good cause for the delayed action.

Recommendation

Eliminate any restrictions on reopenings that are designed to correct minor errors and omissions allowing such a reopening request to be made prior to the exhaustion or expiration of appeal rights. Further, CMS should modify the reopening standards to establish rights and responsibilities on an equal basis for Medicare beneficiaries, providers of services, and Medicare contractors.

Expedited Proceedings

The proposed rules implement an important new right of appeal set out in the BIPA provisions regarding an expedited appeal process available to beneficiaries subject to service terminations or discharge. It is important that CMS recognizes

that the expedited appeals proceedings do not include reductions in an ongoing course of service. However, the proposed rules need additional clarification to address terminations of services where there are no physicians' orders or appropriate certifications to continue care. The BIPA provisions and the proposed rules properly require that a physician certify the failure to continue services is likely to place the beneficiary's health at risk, but do not directly explain that other technical requirements for the continuation of services and coverage must be in place as well. For example, a strict reading of the proposed provision would allow for a right of expedited appeal even in situations where the physician has ordered the discontinuation of home health services or refused to certify the patient as confined to the home. Allowing an expedited appeal in such circumstances would raise serious questions regarding the authority of the home health agency to continue to deliver care during the pendency of the appeal or the right to secure Medicare coverage thereafter.

The proposed rules on the expedited appeals process also indicate that the provider cannot bill a beneficiary for the disputed stay of services until the beneficiary has received an expedited QIC determination. While such an approach may be necessary to fairly effectuate the expedited appeal rights of Medicare beneficiaries, it places providers of services at financial risk without any consideration of that risk within current reimbursement rates.

Recommendation

CMS should clarify that other technical requirements for Medicare coverage be in place, such as physicians' orders for continued care and certification of homebound status, in order to trigger any expedited appeal rights. Further, CMS should require that Medicare beneficiaries be informed through the initial determination that financial liability for noncovered care will exist in unsuccessful expedited appeals. Finally, CMS should adjust payment rates to those providers whose existing payment rates do not include any bad debts resulting from the inability to collect after a beneficiary's unsuccessful expedited appeal.

Representative Fees

The proposed rules indicate that no award of attorneys' fees may be made against the Medicare Trust Fund and that a provider acting as a representative beneficiary may not charge the beneficiary with any fee associated with representation. These proposed rules do not address the application of the Equal Access to Justice Act to adversarial administrative proceedings that may occur under the new rules allowing CMS or its contractors to achieve party status. Further, these rules do not address representation of beneficiaries by non-provider individuals or entities. It appears the only rule governing representative's fees to beneficiaries allows for fees to be limited to no more than 25 percent of past due benefits, a standard applicable to Social Security cases.

Recommendation

The proposed rule should be revised to reference the availability of fees under the Equal Access to Justice Act under those circumstances where the administrative proceeding is adversarial. Further, the proposed rules should be modified to specifically address any fee limitations applicable to a Medicare appeal by a non-provider representative or Medicare beneficiary.

New Issues on Appeal

The proposed rules address the introduction of new issues at the ALJ stage of appeal. However, the rules do not address those circumstances where the contractor or QIC raise new issues distinct from that originally in dispute. The initiation of new issues for review at other steps in the appeals process have often created great confusion for Medicare beneficiaries and health care providers while forcing the introduction of new evidence that is otherwise not contemplated as necessary.

Recommendation

Prohibit Medicare contractors and QICs from raising new issues during an appeal. Any issues distinct from those in dispute should be raised through the reopening process.

Failure to Meet Time Limits for Review

The rule establishes timelines for completions of all levels of review as required by BIPA. While the parties are given rights to accelerate the appeal in the event

of the appellate level failure to meet timeliness standards, CMS should consider the imposition of additional contractor penalties where they fail to comply with required time limits.

Recommendation

Implement penalties, including payment of interest, when CMS contractors fail to complete appellate review within the established timeframes.

NAHC wishes to extend the thanks of the entire home health and hospice community for CMS' efforts to issue this proposed rule. The difficulties attendant to a wholesale restructuring of the appeals process are readily recognized and NAHC appreciates CMS good faith efforts to implement these important BIPA provisions and to modernize the appeals structure otherwise. We look forward to the publication of the final rule.

Very truly yours,

William A. Dombi
Vice President for Law
National Association for Home Care & Hospice

ATTACHMENT 2

OASIS SIMPLIFICATION RECOMMENDATIONS BY THE HOME HEALTH INDUSTRY TO CMS ADMINISTRATOR THOMAS A. SCULLY

October 12, 2001

Mr. Thomas A. Scully
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
314G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Scully:

All of our organizations (listed below) representing home health care thank you for the opportunity to submit recommendations for streamlining the Outcomes and Assessment Information Set (OASIS) data set and related requirements. We understand that the Centers for Medicare and Medicaid Services (CMS) is currently considering reducing paperwork and streamlining patient assessment requirements for home health providers as was done previously for other Medicare providers. Our purpose is to provide input to that process.

Because our focus was on reviewing OASIS from clinical, practical and consumer viewpoints, we did not address OASIS case mix payment issues, which we believe should be reviewed separately by CMS and provider representatives within the context of case-mix reform. However, we did address the costs that providers have incurred—and continue to incur—for meeting OASIS regulatory mandates.

The formation of this task force was in response to the hundreds of letters, e-mails and phone calls that the provider organizations have received from their memberships. While there is industry-wide support for an outcome-based assessment process, members have consistently requested that CMS eliminate the non-essential and redundant OASIS components and requirements. They continue to plead for OASIS reform because of the toll that the increased OASIS paperwork is having on their ability to recruit and retain nurses and because of the staggering costs involved in implementing and maintaining OASIS regulatory compliance.

OASIS is often cited as the number one reason why nurses are leaving home health care. As a result, it has exacerbated the already scarce supply of available and qualified nurses nationwide. A home health nurse typically must spend more time complying with federal paperwork requirements than providing hands-on care during one 60-day episode of patient care. In addition, the cost of OASIS far exceeds the reimbursement since home health agencies are not compensated for the cost of professional staff time or for the technology that has been necessary for OASIS and PPS implementation.

Finally, since the OASIS data set is not a comprehensive assessment, home health agencies are required to incorporate OASIS into the individual agency's comprehensive assessment process. However, surveyors have adopted a punitive approach toward agencies whose comprehensive assessments do not fit into their subjective view of how a comprehensive assessment should appear.

GENERAL RECOMMENDATIONS

1. The requirements to collect and transmit OASIS information should only apply to Medicare patients because:
   - The policy of requiring OASIS for all patients does not comport with CMS' goal to move home care oversight from the current process-driven orientation to an outcome-driven orientation. We believe that collecting OASIS data from only Medicare patients (and measuring their outcomes) is likely to be the best and most efficient process for determining an agency's overall level of quality care because it is a clean set of data from a more homogenous patient population. If an agency is consistently achieving good outcomes for its Medicare case load, it would be highly unlikely that the same agency would provide less quality care to its non-Medicare patients (especially in light of requirements to comply with all other Medicare conditions of participation for all patients.)
   - CMS's primary rationale for mandating OASIS requirements—as stated in the OASIS final regulation—is to use this information for payment purposes for Medicare beneficiaries:

     The immediate publication of rules requiring the collection and reporting of OASIS data and OMB approval of these requirements (OASIS) pursuant to the Paperwork Reduction Act of 1995 are essential because these data are required for the development of the home health prospective payment system, required by statute in October of 2000 (Page 3765 of the January 25, 1999 Federal Register).

   In other words, OASIS was mandated for payment purposes before its original intended use for measuring patient outcomes (i.e. quality of care). Collecting only Medicare data now is consistent with the current use of OASIS.

   - Limiting OASIS to Medicare patients is especially important because nurses and patients alike are experiencing difficulties due to the length and frequency of assessments. This is particularly true in cases where patients have minimum to moderate health care needs. Limiting OASIS to Medicare patients will help alleviate stress on patients and nurses and reduce the cost of OASIS administration for home health agencies.
2. Allow home health providers to have access to the studies on the validity and reliability of OASIS data and adverse event measurements, which are now being used to evaluate home health agencies with potential negative consequences.
3. Provide rationale for why many of the items (that are indicated below by a "*") were determined by CMS to be good indicators of quality care. For these items, and for changes to OASIS in general, we also strongly recommend that CMS develop a process to evaluate the suitability of any OASIS items whose need is not readily apparent. The process should include providers, researchers and consumer advocates and contain a general public comment phase. Each item on the form should be required to have above average inter-rater reliability and should be judged by its incremental performance in patient classification systems or outcome risk adjustment methodologies, or be necessary as an outcome measure. Any review process must be designed to explicitly balance the natural desire for more information with the need for efficient data collection and patient privacy.
4. Allow agencies to use a single, universal form for all OASIS data collection time points (i.e., start of care, transfer/discharge, resumption/change of care and recertification). Questions specific to a particular assessment would be easily identified on the universal form. A universal form would prevent the confusion over what form to use for a particular visit. If a nurse mistakenly fills out the wrong form, which may be nearly identical to other OASIS forms, he or she must complete the minimum 45 minutes of OASIS paperwork again.
5. Eliminate the current OASIS assessment requirement for significant change in condition. The ambiguity of what is considered to be "a significant change in condition" has essentially forced each home health agency to establish its own significant change policy, particularly involving cases where there is not a hospitalization. This subjectivity leads to questionable validity and usefulness of the data for outcome measurements.
6. Eliminate the requirement to perform an OASIS assessment in cases where it is known that a patient will require only a single visit or is a predictable LUPA patient.

7. Allow any practitioner of a qualifying service to conduct the initial assessment and comprehensive assessment regardless of whether skilled nursing is included on the plan of care.
8. Amend the required "complete and lock dates" as follows: 10 calendar days to complete OASIS and 14 calendar days from the day of completion to enter and lock the data.
9. Revise the guidelines for the OASIS resumption of care (ROC) assessment so that it is only required for patients who have been hospitalized for more than 72 hours. The need for a ROC could serve as a proxy for what is considered to be "a significant change in condition" until a better definition is developed and agreed on by CMS and national provider representatives.
10. Increase reimbursement to home health agencies to reflect the true costs of OASIS, including the cost of professional time spent training and completing forms, and the cost of technology systems necessary to implement OASIS for OASIS and PPS compliance. A recent report by the General Accounting Office (GAO) clearly identified "an increase in time spent for patient assessments after the implementation of OASIS mandate. These HHAs also reported additional costs associated with verifying and transmitting data to HCFA, as well as with training new hires to collect OASIS data." (*OASIS Data Use, Cost and Privacy Concerns*, GAO, January, 2001). It is important to point out that the GAO study only focused on the extra time associated with start-of-care assessments. Although we disagree with GAO's assessment that HHAs will be able to finance these extra costs from PPS payments, we do generally agree with the additional magnitude of the extra costs as identified in the GAO study. CMS' before-the-fact assertion that agencies will have no additional costs after the going through the learning curve is erroneous and needs to be reexamined in light of the significant actual experience to the contrary.
11. Inform home health agencies and surveyors that basic demographic data is not required on the comprehensive assessment form if available elsewhere on the agency record for formatting and reporting to the State Agency.
12. Eliminate the requirements to perform two or more assessments when those particular assessments fall within a close proximity of time (e.g. cases involving a change in payer) and when the additional assessment is performed to accommodate the CMS systems rather than for clinical purposes.
13. Eliminate requirements to make home health visits that are "non billable" solely for the purpose of fulfilling CMS OASIS time frames. Allow completion of the assessment on the next billable visit. These requirements have increased the cost to the Medicaid waiver programs for long-term and chronic patients.
14. Require CMS compliance with coding rules, including ICD–9 coding, as mandated by HIPAA.
15. Eliminate duplication and inconsistency between OASIS and the 485 (plan of care) forms.

RECOMMENDATIONS FOR INDIVIDUAL OASIS ASSESSMENT ITEMS

The task force identified the following assessment items as items that should be either: (1) deleted for identified reason; (2) deleted unless it is determined after examination that the item is useful for casemix and/or risk adjustment; (3) revised; or (4) redefined to improve the item's comprehension by nurses and therapists (several of these questions and options are so intricate that precision is lost in the collection of the data).

MOOOO	Description	Action/Reason
M0140*	Race/Ethnicity	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful.
M0160*	Financial Factors	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful.

MOOOO	Description	Action/Reason
M0190	Inpatient diagnosis	Delete (unnecessary and unreliable responses).
M0200*	Treatment change	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful.
M0210	Changed diagnosis	Delete (unreliable responses).
M0220*	Prior conditions or inpatient stay	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful.
M0260*	Overall prognosis	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful. In addition, the item is already documented on the 485 form.
M0270*	Rehab prognosis	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful. In addition, the item is already documented on the 485 form.
M0280	Life expectancy	Delete (inherently subjective).
M0290*	High risk factors	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful.
M0310–M0330	Living arrangements	Limit item to only start-of-care (SOC) assessment. Complete thereafter only if a change in living arrangement occurs.
M0340–M0360	Living arrangements	Retain and simplify to “yes” “no” responses.
M0400	Hearing	Simplify to general terms that clinicians can easily understand.
M0420–M0430	Pain	Examine other more reliable pain scales.
M0440	Skin lesions	Redefine to identify active pathology and specify the types of lesions that would be considered “skin lesions” in a manner that is understandable to the nurse and eliminates his/her subjectivity.

MOOOO	Description	Action/Reason
M0460	Most problematic wound	Redefine using medical terminology that is understandable to the nurse and eliminates subjectivity. This is especially important because a "most problematic wound" may be a different wound for each assessment.
M0468	Stasis ulcers	Redefine to include arterial, venous diabetic and neuropathic ulcers.
M0560–M0620	Neuro/Emotional/Behavioral	Redefine to improve reliability of assessment by simplifying options in a manner that is understandable to the nurse, eliminates subjectivity, and facilitates a level of trust between provider and patient who may have issues related to depression. In addition, the items should be optional if the patient reserves his/her right to privacy.
M0630	Psychiatric Nursing Services	Delete (very limited provision of psychiatric nursing in home care).
M0640–M0800	ADLs/IADLs/Medications	Delete "prior" column (unreliable and non-verifiable responses).
MO720–MO770	Instrumental Activities of Daily Living (IADLs)	Delete "current" column (unreliable responses).
M0830–M0840*	Emergent Care	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful.
M0890–M0900*	Inpatient Reason/Reason for Nursing Home	Examine and determine the usefulness of this item for casemix and/or risk adjustment; delete item if it is determined to be not useful.

The OASIS Provider Task Force would appreciate the opportunity to discuss our recommendations with you and your staff in person. Such a meeting would facilitate collaboration between CMS and constituent organizations thus maintaining the spirit of CMS' "open door" initiatives, which have been deeply appreciated by the home health care and hospice communities.

Contact persons for the task force are Kathy Thompson, Visiting Nurse Association of America (VNAA) (202/737–3707), and Mary St. Pierre, National Association for Home Care. (NAHC) (202/547–7424).

Thank you again for your consideration of our recommendations.

Sincerely,

American Hospital Association
American Home Care Association
American Association for Homecare
Connecticut Association for Home Care
Gentiva Health Services
Medstar Health VNA, Washington, D.C.
National Association for Home Care
Visiting Nurse Associations of America

cc:
Dallas R. Sweezy, Director of Public Affairs, CMS
Rob Foreman, Director of the Office of Legislation, CMS
Tom Hoyer, Director of the Chronic Care Purchasing Policy Group, CMS

Bob Wardwell, Director of the Division of Community Post-Acute Care, CMS
Pat Bousliman, Professional Staff Member, Senate Finance Committee
Susan Christensen, Legislative Assistant, Office of Congresswoman Nancy Johnson (R–CT)
Deborah Williams, Professional Staff Member, House Ways and Means' Health Subcommittee

Chairman JOHNSON. Thank you very much, Ms. Wolf. Dr. Ryan.

STATEMENT OF JUDITH A. RYAN, PH.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, EVANGELICAL LUTHERAN GOOD SAMARITAN SOCIETY, SIOUX FALLS, SOUTH DAKOTA, ON BEHALF OF THE AMERICAN HEALTH CARE ASSOCIATION

Dr. RYAN. Good morning. Thank you for inviting me to provide perspective on the progress of regulatory reform in long-term care. I am Dr. Judith Ryan, President and Chief Executive Officer of the Evangelical Lutheran Good Samaritan Society.

It has been my privilege and experience to watch the evolution of regulation in long-term care for more than 45 years now from a number of perspectives: as a community health nurse; as executive director of the American Nurses Association; and as the chief quality officer of Lutheran General Health System; the associate director for the University of Iowa Hospitals and Clinics; and now I lead the Good Samaritan Society, which is a long-term care organization, deeply rural. We have grown large not by marketing plans, but by responding with over 80 years of service to small rural communities who have needed help in providing older adult services for the elders who are there.

Over that period of time we have become the largest not-for-profit provider of long-term care in the country. We have 250 sites of care, and care for 27,000 residents across 25 States. We employ nearly 24,000 people.

I speak today on behalf of the members of the American Health Care Association, and testify today not to ask for less or for more regulation, but to ask for a more accountable regulatory process in long-term care. We believe that such a process will benefit providers of care as well as their residents and staff.

I would like to comment in three major areas: regulatory solutions that we think need to be addressed in long-term care oversight; legislative improvements that we still think are necessary; and to share strides in quality improvement we believe that the long-term care profession is making.

With regard to regulatory reform, as you know, in 1986 it was the Institute of Medicine's Committee on Nursing Home Regulations, in its final report, that provided the impetus for Congress to enact major regulatory reform in long-term care. Passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA) ushered in an era of change in nursing facilities' approach to resident care.

The OBRA was intended to move long-term care in new directions. It has moved it in a lot of new good directions. However, OBRA enactment did not modify the basic Federal regulatory approach to quality, and that omission has forced perpetuation of a

system that is based on external standards and measures of quality that were current in the 1980s.

We know much more about improving quality now and have better tools to measure that quality, and we believe that the regulatory process must be updated to allow and to encourage us to use them. In fact, in three of the States in which Good Samaritan has a large presence, these States have asked for Federal Government waivers to allow them to test outcome-based measures of quality, and to increase their oversight of poor-performing facilities.

Those waiver requests have been denied by HHS because there is not that authority under the Medicare waiver. I have brought a graphic depiction, which you can see up here, which looks at the external regulators with which each nursing home must comply. I have seen similar graphs in acute care, but they are different kinds of graphs. Those charts in hospitals focus on voluntary accreditation by Joint Commission, on accreditation and certification by the various professional societies, etc.

You will note that in long-term care it is the Justice Department that sometimes oversees matters of clinical care and treats them in criminal matters. We also have the State survey process which works under contract with CMS, and a number of direct regulations that relate to public reporting, and to the payment systems for long-term care that are under CMS directly.

It is a regulatory maze and it is many times duplicative and punitive. It has been said that in acute care we talk about medical error, and in long-term care we talk about fraud and abuse. In reality, acute and long-term care include a continuum of services that we must provide to our older adults. We don't suggest that regulations be eliminated, we just suggest that they be made smarter. There are legislative solutions that would help, and this Committee has given leadership by paying attention to a good number of them.

The long-term care profession supported the Medicare Regulatory and Contract Reform Act in the last session of Congress and will do so again in the 108th. Your legislation will reduce the appeals backlogs. The payment appeals and information-sharing provisions of your legislation will help providers better navigate the maze of guidance from CMS fiscal intermediaries, and you address other important program changes. We applaud your leadership and will urge the Senate to follow your lead.

Another area we urge you to address are instances where the nursing home regulatory and enforcement system actually impedes quality improvement. I think there are three examples I would like to lift up:

One is the nature of the relationship between the government as regulator and the providers of service. Government inspectors are forbidden from providing consultative services to nursing facilities, from sharing best practices, making suggestions to improve care.

Second, nursing homes are often fined for following the orders of a patient's physician, forcing them to choose between a regulatory fine or the liability that comes with disregarding the orders of the patient's doctor.

A third example occurs when nursing homes are automatically forced to terminate their training programs for certified nursing

aides for 2 years. These regulations usually hurt quality improvement more than they help.

These and several other impediments to quality improvement are corrected in the Medicare and Medicaid Nursing Home Quality Improvement Act that was introduced last year by Congressman Camp on this Committee. I would like to thank you, Congressman Camp, for that work, and Congressman McDermott, and urge other Members of the Committee to cosponsor that bill when introduced this session. We believe it will help us to focus the nursing home oversight system on quality improvement.

Providers of care are taking initiative. Leaders in long-term care have known for a long time that we have got to remove our focus from regulatory compliance and focus rather on making remarkable improvements in the quality of long-term care and services. Two major initiatives have grown out of early discussions among leaders in long-term care, leaders of both the profession and the trade and legislative advocacy groups: CMS's Nursing Home Quality Initiative and the Quality First Initiative. Commissioner Scully referenced the first. That work has really enabled us to identify measures of quality, data that we already have, that we think go a long way to helping inform consumers about the quality that a facility is offering. Those measures have been validated by CMS and a system for reporting them has been developed, tested, and rolled out. An ongoing system of professional consultation to nursing facilities is being put in place under CMS's quality improvement organizations. That work is going forward very effectively.

The second initiative has been the long-term care profession's Quality First Initiative, which was announced last year, with an objective of building a covenant to promote healthy, affordable, accountable, and ethical long-term care. That commitment is on the part of the providers and professionals themselves.

I think these two quality initiatives give pretty good evidence that the government, the professionals, the providers, are working more effectively together.

One other comment. I was privileged to serve on Secretary Thompson's Advisory Committee on Regulatory Reform, chaired by Dr. Doug Wood, and have great respect for that undertaking.

We discovered that there is great potential for containing costs and improving quality if we can better align both the payment and regulation of Medicare and Medicaid programs. Many of the Secretary's Committee recommendations focus on that. There is one piece of unfinished business that will take legislative action that can't be accomplished by the regulatory authority the Secretary has. That is described in Appendix C of the Secretary's Advisory Committee on Regulatory Reform report as the number one piece of unfinished business.

The Secretary's Advisory Committee on Regulatory Reform chose to report those things that we discussed but couldn't reach closure because of time constraints. The wording of that is in my written testimony. It encourages demonstration of unified service delivery to those persons dually eligible for both Medicare/Medicaid; testing of regulations in limited geographic areas before implementation; greater flexibility in testing the efficacy of alternative ways to sur-

vey nursing facilities; and stimulating use of information systems across the Medicare and Medicaid programs.

I thank you for the time to be with you, and for the time you serve on the Committee, and I hope that you will take these things to mind.

[The prepared statement of Dr. Ryan follows:]

Statement of Judith A. Ryan, Ph.D., President and Chief Executive Officer, Evangelical Lutheran Good Samaritan Society, Sioux Falls, South Dakota, on behalf of the American Health Care Association

Introduction of the Speaker

Good morning, Madam Chairman and members of the subcommittee. Thank you for inviting me to provide perspective on the progress of regulatory reform in long-term care.

I am Dr. Judith Ryan, President and Chief Executive Officer of The Evangelical Lutheran Good Samaritan Society. The Society is a membership organization of men and women collectively engaged in building communities of care for older adults and others in need across the country. I have watched the evolution of regulation in long-term care for forty five years in various capacities—as a community health nurse, executive director of the American Nurses Association, senior vice president and chief quality officer for Lutheran General Health Systems and Associate Director of the University of Iowa Hospitals and Clinics.

I now lead a long-term care organization that is deeply rural. We have grown over the 80 years of our history by partnering with communities who have recognized the need for help to provide facilities, programs and services for older adults. Over 80 years of service, the Society has become the largest not-for-profit provider of long-term care and senior services in the country. We offer senior housing and skilled nursing options in more than 250 sites of care across 25 states, serve 27,000 residents and employ nearly 24,000 staff. Our sites of care are linked together by cutting-edge communications technology: by voice and telecommunications, Intranet and satellite.

I speak today on behalf of all members of the American Health Care Association, the national organization representing over 12,000 providers of long term care who serve over 2 million elderly and disabled people annually and employ over 1.5 million people. We are testifying today not to ask for less or for more regulation, but to ask for a more accountable regulatory process. We ask for a process through which all stakeholders can work together to promote and maintain quality care for all Americans. Such a process will benefit providers of care as well as their patients and their staff.

I am here to discuss three areas:

1. Regulatory solutions in long term care oversight
2. Legislative improvements to long term care oversight
3. Strides in quality improvement made by the long term care profession

Regulatory Reform in Long-Term Care

In long term care, as in the other sectors of our health care system, we labor under the inequities of very difficult payment and review policies, and we are deluged with paperwork as you will hear from the other witnesses. In fact many of our best nurses leave long term care to work in hospitals or other settings where the paperwork burden is less. Nevertheless, we have an additional regulatory problem that is unique to long term care, and causes even more difficulty in patient quality than the other two problems combined. That difficulty comes when the regulations start impeding the quality of care that our patients are receiving.

Twenty years ago this year, the Institute of Medicine's Committee on Nursing Home Regulation was convened to "*serve as the basis for adjusting federal (and state) policies and regulations governing the certification of nursing homes so as to make those policies and regulations as appropriate and effective as possible.*" The final report, "Improving the Quality of Care in Nursing Homes" issued in 1986, provided the impetus for Congress to enact major regulatory reform in long-term care. Passage of the Omnibus Budget Reconciliation Act in 1987 (OBRA '87) ushered in an era of change in nursing facilities' approach to patients' care. Congress made the care mandate very clear: All certified facilities must: ***". . . attain or maintain the highest practicable physical, mental and psychosocial well being of each resident."***

The OBRA '87 mandate was intended to move care in new directions, and it did. However, the statute did not modify the basic federal regulatory approach to quality. That omission has forced perpetuation of a system that is based on expectations and measures of quality that were current in the 1980's. We know much more now about promoting quality and have better tools to measure it than we did back then. The regulatory process must be changed to allow and encourage us to use them. Today both regulators and facilities must be involved in a dynamic system of quality improvement, using the same principles of continuous quality improvement. It is time to move to such a system and regulatory reform will take us there.

In fact, Madam Chairman, each of the three states in which the Good Samaritan Society has the largest presence have asked the federal government for a waiver to allow them to test outcome-based measures of quality, and to increase their oversight on poor performing facilities. Those waivers from the States of North Dakota, South Dakota, and Minnesota were denied by HHS due to lack of Medicare authority. This is but one example of how static statute and regulation has prevented quality measurement and improvement from moving forward.

For the past 15 years, those of us most accountable for providing quality services to patients in long-term care—physicians, nurses, social workers, therapists, pharmacists, certified nursing assistants, administrators, residents, families and consumer advocates—have had to become increasingly focused on compliance with external expectations of quality and static regulations. This occurs at the expense of continuous quality improvement and attention to individual patients' needs. For example, nursing homes are regulated by dozens of agencies, and from all sides. I have brought a graphic depiction of the external regulators with whom each nursing home must comply. It is difficult to see how staff have time for caregiving. Here are just a few of the responsibilities we are focused on daily:

- State survey, licensure and accreditation requirements
- Regulations related to certification for participation in government payment systems (Medicaid and Medicare)
- Regulations related to assessment and documentation of the resident's functional status, related plans of care, and quality measures.
- CMS reimbursement policy that tailors patient assessment to payment levels.
- Standards for privacy, patient rights, and business transactions under HIPAA.
- Office of Inspector General (OIG) policies and programs pertaining to fraud and abuse.
- CMS' mandatory program of reporting quality measures to the public.

This is not to suggest that regulations be eliminated but that they be made "smarter." We are asking that the processes used to determine compliance and judge quality and patients' outcomes be modified and updated.

Legislative solutions

Your Committee, Madam Chairman, has taken important steps forward toward this end. It is now my hope that your committee can provide the impetus to make these reforms a reality.

This is why the long-term care profession strongly supported the Medicare Regulatory and Contracting Reform Act (MRCRA) in the last session of congress, and do so again in the 108th Congress. Our subjective and inflexible oversight system necessitates that providers constantly appeal erroneous citations that in turn creates backlogs of appeals at the Administrative Law Judge (ALJ) and Departmental Appeals Board (DAB) levels. Furthermore, because our oversight system is punitive in nature, and because the first level of appeals is before the very people who issued the citation in the first place, the ALJ is really the first impartial appeal we face. Your legislation will reduce this backlog by increasing ALJ and DAB resources to hear these cases. The payment appeals and information sharing provisions of your legislation will help providers better navigate the maze of guidance from the CMS, the FIs, and other program changes. We applaud your leadership and will urge the Senate to follow your lead. Another area we urge you to address are the several instances where the nursing home regulatory and enforcement system actually impedes quality improvement. Let me discuss three examples. First, government inspectors are forbidden from helping care providers improve quality by suggesting best practices, or even praising good care. Second, nursing homes are often fined for following the orders of the patient's physician—forcing them to choose either a regulatory civil monetary penalty (CMP), or the liability that comes with disregarding the orders of the patient's doctor. A third example occurs when nursing homes that

are fined $5000 or more are automatically forced to terminate their training programs for certified nurses aides—for two years. Even if the deficiency is cleared up within a day, the provider's ability to train more staff is gone for two years. This usually hurts quality improvement more than it helps, especially in rural areas where there are no training programs nearby.

These and several other impediments to quality improvement are corrected in the Medicare and Medicaid Nursing Home Quality Improvement Act (HR 4030) that was introduced last year by Congressman Dave Camp on this committee. I'd like to thank Congressman Camp, Congressman McDermott, and the other cosponsors for their leadership in quality improvement and urge the other members of the committee to cosponsor the bill and help us make the nursing home oversight system more focused on improving quality.

Providers of care take the initiative

In the late 1990s, leaders in long-term care recognized that we had to recapture a sense of professional and individual accountability to make remarkable improvement in the quality of long-term care and services. These leaders met to consider how we might align our individual organizational quality initiatives and work more effectively with government to manage change.

Two major initiatives grew out of those early discussions:

1. CMS's Nursing Home Quality Initiative, in which:

- Measures of quality have been defined and validated by CMS;
- A system for reporting these measures to the public has been developed, tested and rolled out; and
- An ongoing system of professional consult in continuous quality improvement is currently being put in place by the Quality Improvement Organizations.

2. The long-term care profession's Quality First Initiative, which was announced in 2002 with the objective of building a covenant by and among all representatives within the profession to promote healthy, affordable, accountable and ethical long-term care. Quality First is a comprehensive, measurable commitment to quality that we believe nursing homes will embrace. It is, in essence, a promise from providers to patients and their families that nursing homes will deliver the high quality care that America's seniors deserve.

Quality First consists of seven principles that have been jointly endorsed by AAHSA, the Alliance, and the American Health Care Association (AHCA).

The seven core principles are as follows:

- *Continuous Quality Assurance and Quality Improvement;*
- *Public Disclosure and Accountability;*
- *Patient/Resident and Family Rights;*
- *Workforce Excellence;*
- *Public Input and Community Involvement;*
- *Ethical Practices; and*
- *Financial Stewardship*

Quality First further calls for the creation of a National Commission on Nursing Home Quality that will report progress toward achieving improved quality. The panel will identify opportunities for quality improvement; recommend annual quality improvement goals; and assess the impact of the voluntary quality initiative on care and services.

In addition to achieving a uniform commitment to quality, the goal of Quality First is to build consumer trust through achieving excellence in care and service delivery.

I believe these two quality initiatives indicate the desire on the part of the government and provider community to work toward a common goal of improving quality; however, more needs to be done.

Regulatory Reforms

Madam Chairman, I was privileged to serve on Secretary Thompson's Advisory Committee on Regulatory Reform (SACRR), chaired by Dr. Douglas Wood, and have great respect for this undertaking. During the eleven months of work of this Committee, I have seen first hand how well intended regulations can have the effect of impeding quality. During our work together, Committee members learned that consumers, consumer advocates, beneficiaries, providers, suppliers, the business community, researchers and public officials all reject the current regulatory and payment frameworks for long-term care. This overwhelming vote of "no confidence" pro-

vides the necessary societal and political mandate for Congress to seriously consider meaningful reform.

We also found great opportunities for streamlining programs and making them more beneficiary focused. For example: The elderly and persons with disabilities need both medical care, and help with personal needs and activities of daily living. Medicare pays for the former, and Medicaid pays for part of the latter. The two programs are administered as separate programs. Six million people are eligible for both programs.

There is tremendous potential for containing cost and improving quality of care and services if we can better align both payment and regulation in the Medicare and Medicaid programs. Many of the 255 SACRR recommendations address this issue.

Madam Chairman, the Medicare Regulatory and Contracting Reform Act passed by the House during the 107th Congress addressed many of the reforms embraced by the SACRR. The Centers for Medicare and Medicaid Services, (CMS) can implement many of SACRR's recommendations through administrative action and we strongly encourage the agency to take this step. However, there is unfinished business that warrants Congressional action. Appendix C of SACRR's report contains unfinished Committee business—recommendations that were proposed by SACRR and either formally discussed or put forth for Committee consideration, but not brought to closure because of time constraints.

The #1 piece of unfinished Committee business reads as follows:

"Expand Medicare waiver authority, selectively, beyond the current limited authority to waive coverage and reimbursement, to accomplish several high priority goals of the Committee, including but not limited to:

- ***Demonstrations of unified service delivery to Medicaid/Medicare dual eligibles.***
- ***Testing of regulations in limited geographic areas before requiring national implementation.***
- ***Allowing greater flexibility to test the efficacy of alternative State survey protocols for skilled nursing facilities/nursing facilities, as per recommendation #213 (Multiple Reviews);***
- ***Enabling providers to access government data for the purpose of improving quality of care, while retaining system security and patient privacy protections."***

Madam Chairman, in the name of regulatory reform in long-term care, we strongly urge that SACRR's #1 piece of unfinished business be introduced as legislation in the 108th Congress.

Concluding Comments:

In conclusion, all of us—beneficiaries, providers, suppliers, lawmakers, regulators and consumer advocates—need to make a disciplined commitment to remarkable improvement in the quality of long-term care:

- The consumer and consumer advocate must commit to systems that will enable residents and families to exercise informed choice.
- The government must commit to avoid unintended consequences of regulation, and to observe and continuously improve the impact of regulation in the real world.
- Providers and suppliers must make a disciplined commitment to adhere to principles of continuous improvement, conduct formal programs of continuous quality improvement, and to report outcomes publicly.
- And finally, all stakeholders must make a joint commitment to using technology to share data that is patient specific across sites of care and time in order to integrate the patient's experience with episodes of acute care, skilled nursing care, home health care, and community-based long-term care.

While these challenges are formidable, Madam Chairman, your legislation, Congressman Camp's legislation, and the ideas put forth by the Secretary's Commission give us hope and the tools to achieve meaningful reform in the regulation of long-term care. We pledge to work with you to bring about these important changes. Thank you for your leadership.

Chairman JOHNSON. Thank you very much. Dr. Carius.

STATEMENT OF MICHAEL CARIUS, M.D., IMMEDIATE PAST PRESIDENT, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS, NORWALK, CONNECTICUT, AND FOUNDING MEMBER, ALLIANCE OF SPECIALTY MEDICINE

Dr. CARIUS. Thank you, Chairman Johnson, Ranking Member Stark, and Members of the Subcommittee for the opportunity to testify here today. I am Dr. Michael Carius, Immediate Past President of the American College of Emergency Physicians (ACEP), and a Founding Member of the Alliance of Specialty Medicine. I am here today representing nearly 23,000 emergency physicians, and more than 160,000 physician specialist members of the 13 medical specialty societies and associations that comprise the Alliance.

I am here today to discuss the Medicare regulatory reform provisions in H.R. 4954, the actions CMS has taken towards regulatory relief, and what remains to be done in the future. I will also address the Emergency Medical Treatment and Labor Act.

Today, liability costs and reimbursement reductions have taken their toll on the practice of medicine. Government regulation has compounded our paperwork, which is demoralizing for physicians who are in the business of patient care. Ultimately, patient care is jeopardized when physicians are forced to spend hours filling out a blizzard of bewildering paperwork to comply with enormous and complex Federal health care regulations, particularly those of Medicare, Medicaid, and now HIPAA.

We applaud the Committee's efforts during the last Congress to reduce and streamline Medicare regulations, and encourage you to continue your effort this year.

The ACEP and the Alliance have long supported the goal of EMTALA to prevent discrimination in the delivery of emergency medical care. Since 1986, EMTALA's impact on health care has been great, but over the years, regulations, guidance and court decisions have caused this law to be increasingly problematic for emergency care. We are encouraged by the draft regulations published in May 2002 which indicate that CMS has thoughtfully reviewed the regulatory language and guidance it has promulgated. From this, we anticipate comments from physician and hospital groups will lead to further improvements to the final regulation.

However, additional steps need to be taken. The ACEP and the Alliance support section 844, which contains additional EMTALA improvements. We believe payment for medical screening examination and stabilizing treatments should be based on the presenting condition, not on the final diagnosis, which has been used by both the public and private payers to deny payment and which is inconsistent with the EMTALA duty to screen and stabilize.

Enforcement actions have been inconsistent, driven by poor patient outcomes, questionable complaints, and adversarial attitudes. The ACEP and the Alliance recognize that EMTALA definitions are legal, not clinical, and urge that investigations focus on whether the medical screening examination process was discriminatory and not on clinical or quality-of-care concerns. We view heavy-handed and uneven enforcement as one of the greatest threats to a collapsing emergency medical care system.

Section 844 also addresses the role of peer review in EMTALA investigations. Currently, if peer review is obtained, CMS rec-

ommends but does not require agencies or regional offices to use board-certified physicians. However, peer review often does not occur because of short review times required by CMS.

The ACEP and the Alliance urge Congress to mandate early peer review and require reviewers to be board-certified physicians practicing in the specialty related to the alleged violation. In addition, peer reviewers should also be trained in the EMTALA law and regulations applicable to medicine. The ACEP and the Alliance support quality EMTALA enforcement and peer review participation and would willingly participate as peer reviewers.

The uncertainty surrounding both initiation and closure of an EMTALA investigation is one of the most vexing aspects for physicians. We believe quality improvement organizations' peer review reports should be provided to the hospitals and to physicians being investigated concurrently with their delivery to CMS, and we support the notification of providers when the investigation is closed.

The ACEP and the Alliance support the provisions found in section 845. Provider experience, expertise, and input into CMS decision-making regarding interpretation and enforcement of the law would avoid conflict and decision error, and improve compliance consistent with congressional intent.

Emergency departments face a dwindling supply of medical specialists who need to maintain their own practice obligations while endeavoring to provide on-call services to several different hospitals where they may have privileges. This crisis was highlighted recently during President Bush's recent visit to Scranton, where he found only one neurosurgeon who covers two hospitals and a trauma center. One surgeon clearly cannot cover three facilities simultaneously.

Unfortunately, the proposed rule further confuses and increases emergency departments' on-call problems. How will emergency physicians, who urgently need the services of an on-call specialist, find one who is able to come to the emergency department?

The lack of payment for treating and stabilizing uninsured EMTALA-related cases is an underlying problem, and it threatens the viability of our Nation's health care safety net, emergency departments, and trauma centers. The proposed EMTALA technical advisory group must examine this problem.

In conclusion, Federal policy must acknowledge today's environment and develop broader-based approaches to on-call coverage. It also must address funding EMTALA-mandated services, expansion of the EMS infrastructure, and development of a more consistent and pragmatic EMTALA enforcement program.

We believe that the proposed composition of the EMTALA technical advisory group in section 845, which includes broad representation from CMS, including its regional offices as well as the Office of Inspector General (OIG), State reviewers, peer reviewers, and consumers will adequately protect public interest without a Federal Advisory Committee Act requirement, while promoting frank and open discussion of today's difficult issues surrounding EMTALA implementation and enforcement.

This concludes my testimony. I will be happy to provide additional testimony to the Committee as needed. I thank you for the opportunity.

[The prepared statement of Dr. Carius follows:]

Statement of Michael Carius, M.D., Immediate Past President, American College of Emergency Physicians, Norwalk, Connecticut, and Founding Member, Alliance of Specialty Medicine

Thank you, Chairman Johnson and Ranking Member Stark and Members of the Subcommittee for the opportunity to testify. I am Dr. Michael Carius, immediate past president of the American College of Emergency Physicians and a founding member of the Alliance of Specialty Medicine. I am here today representing over 22,000 emergency physicians and more than 160,000 physician specialist members of the 13 medical specialty societies and associations that comprise the Alliance.

You have asked me to speak about the Medicare regulatory reform provisions in H.R. 4954, The Medicare Modernization and Prescription Drug Act passed by the House last year, the actions CMS has taken toward regulatory relief and what remains to be done. You also have asked me to specifically address Emergency Medical Treatment and Labor Act (EMTALA).

I would like to begin by making a few comments about the environment in which American medicine is practiced today. We are practicing in a time when much of the control of our private practice has been taken away by governmental requirements and private sector cost cutting. Liability costs and reimbursement reductions have taken their toll. Government regulation of the practice of medicine and the additional paperwork burden it causes is one of the most wearisome aspects of today's medical practice environment. Chairman Johnson is absolutely correct when she states, "that physicians are frustrated that today's system seemingly is oriented toward and emphasizes policing providers rather than helping them deliver better care."

The enormity and complexity of Federal health care regulations particularly Medicare, Medicaid, and HIPAA regulations make it difficult for physicians to spend time with patients. Instead, physicians and their staff spend hours filling out a blizzard of bewildering paperwork. It is nearly impossible for physicians to recoup the patient care time that compliance with these requirements imposes. We applaud the Committee's efforts during the last Congress to reduce and streamline Medicare regulation and encourage you to continue your efforts this year.

ACEP and the Alliance have long supported the goals of EMTALA. We believe in the intent of EMTALA as an anti-discrimination law. Since 1986, EMTALA requirements have affected us all, but with several versions of the regulations, guidance, and court decisions, EMTALA has had a unique and increasingly troubling impact on emergency medical practice.

It is clear from the draft regulations published in May 2002 that CMS has engaged in a thoughtful review of the regulatory language and guidance promulgated over the years. We are generally pleased with most of the common sense proposals that clarify and refine definitions and demonstrate CMS' efforts to respond to physician and hospital concerns regarding EMTALA compliance. We look forward to the final regulations and anticipate further improvements based on comments from physician and hospital groups.

Legislation passed by the House last year would be largely complementary to CMS' efforts, and passage by the Congress in 2003 would improve physician practice environment. However additional steps need to be taken, and I'd like to focus my comments on a few of the provisions in the Chairman's bill.

ACEP and the Alliance actively support Sec. 844, which contains additional EMTALA improvements.

We believe that the payment for a medical screening examination and stabilizing treatment be based on the presenting condition and services ordered/performed to make a determination of whether or not an emergency medical condition exists. Payment based on the final diagnosis, which has been used by both public and private payers is inappropriate and is inconsistent with EMTALA duty to screen and stabilize.

Currently, enforcement is very unevenly applied across the country. While not addressing enforcement in the draft regulations, CMS has recognized the problems and has a contractor assessing the process disparities across states and regional offices. ACEP and the Alliance recognize that EMTALA definitions are legal rather than clinical, and urge investigators to focus on whether the medical screening examination process is applied in a discriminatory manner, not whether the reviewer has clinical or quality of care concerns. Enforcement actions have been inconsistent, driven by poor patient outcomes, erroneous complaints and adversarial attitudes.

Given the fragile and overloaded condition of our emergency safety net including the specialists it relies on, ACEP and the Alliance view heavy handed and inaccurate enforcement as one of the greatest threats to our already collapsing emergency care system. We believe that Sec 844 will help alleviate these concerns.

Sec. 844 also addresses the role of peer review in EMTALA investigations. Currently, if peer review is obtained, CMS recommends but does not require that the state agencies or regional offices use Board Certified physicians, peer review does not occur often because of the tight review time mandated by CMS. ACEP and the Alliance urge Congress to make early peer review mandatory and that the physician reviewer be a Board Certified physician and actually practicing in the appropriate specialty related to the alleged violation. ACEP and the Alliance believe that peer reports should be made available to the hospitals and physicians involved at the same time the Quality Improvement Organization (QIO) is sending them to CMS.

Physicians involved in peer review should be specifically trained in the EMTALA law and regulations applicable to the practice of medicine. EMTALA violations are legal determinations; they are not medical care violations. Unfortunately, most QIO reviewing physicians understand standards of care related to medical liability rather than the legal nuances of EMTALA. ACEP and the Alliance are very supportive of quality EMTALA enforcement and peer review participation, and would be readily available to participate in peer review at all stages in the process. One of the most vexing aspects of EMTALA enforcement for providers is the uncertainty surrounding the closure of the investigation. ACEP and the Alliance support the notification of providers when the investigation is closed (as found in Sec. 844).

ACEP and the Alliance enthusiastically support Sec. 845. EMTALA Technical Advisory Group.

Provider experience, expertise, and input into CMS's decision making regarding interpretation and enforcement of the law would avoid conflict, decision error, and improve compliance consistent with Congressional intent.

After more than 15 years, the resiliency of the emergency care system and good will of specialty providers is in jeopardy. The lack of payment for treating and stabilizing uninsured EMTALA related cases threatens the fabric of a critical component of our nation's health care safety net of emergency departments and trauma centers. The problems with the "on-call" regulations highlight this issue.

The practical limitations in today's environment are evident. There is a dwindling supply of medical specialists who need to maintain their own practice obligations while endeavoring to provide on-call services to several different hospitals where they may have privileges.

This crisis situation was underscored recently during the President's visit to Scranton, where there is only one neurosurgeon covering two hospitals and a trauma center. One surgeon cannot be in all three places at once. In addition, he cannot continually cancel his scheduled patients or work continuously without a day off.

The proposed regulation provides new and increased flexibility for the surgeon to be on call for more than one hospital simultaneously. Unfortunately, this does not resolve the problem. The proposed CMS regulation requires hospitals to continue to "maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients."

What does this mean? Does it mean the hospitals must provide on-call physicians services or simply maintain an on-call list? What does this mean to emergency physicians trying to find an urgently needed specialist? The current rules, while enhancing flexibility for certain specialists, create uncertainty and ambiguity in how the rules will actually work to provide timely coverage in EDs. A technical expert group can begin to address this, and other serious problems in delivery of emergency care created by EMTALA.

The fundamental underlying question that Congress must answer is how does the federal government propose that hospitals, emergency physicians and other specialists continue to provide uncompensated EMTALA related services in light of the current practice environment? How this issue is resolved will have enormous ramifications to the availability of emergency services in this country, particularly in smaller community hospitals.

Federal policy must acknowledge today's environment and develop broader-based approaches to on-call coverage. Funding for uncompensated care with respect to EMTALA-mandated services, expansion of EMS infrastructure, and more consistent and pragmatic EMTALA enforcement must be addressed also.

Given the sensitivity of many of these issues, we believe there is a more appropriate model to engender frank discussions and generate the compromise needed on these seemingly intractable issues than the FACA model. We note that since the

proposed composition of the EMTALA Technical Advisory Group in Sec. 845 includes representatives from CMS including the CMS regional offices, the OIG, State reviewers, peer reviewers as well as consumer representation, the public interest will be well-protected even without a FACA requirement.

ACEP and the Alliance also support Sec. 821, 823, 834, Provider Education, Medicare Ombudsman, Prepayment review respectively and will provide more detailed written comments on Title VIII to the Chairman.

This concludes my testimony. Again I wish to thank you for the opportunity to testify before the Subcommittee. Thank you.

The American College of Emergency Physicians is a national specialty society representing emergency medicine. With nearly 23,000 members, ACEP is committed to improving the quality of emergency care through continuing education, research and public education. Headquartered in Dallas, Texas, ACEP has 53 chapters representing each state, as well as Puerto Rico and the District of Columbia. A Government Services Chapter represents emergency physicians employed by military branches and government agencies.

The Alliance of Specialty Medicine, is comprised of medical organizations representing over 160,000 specialty care physicians in the United States. The Alliance's mission is to improve access to quality medical care for all Americans through a unified voice of specialty physicians promoting sound federal policy

American Academy of Dermatology Association, American Association of Neurological Surgeons/Congress of Neurological Surgeons, American Association of Orthopaedic Surgeons, American College of Cardiology, American College of Emergency Physicians, American College of Osteopathic Surgeons, American College of Radiology, American Gastroenterological Association, American Society of Cataract and Refractive Surgery, American Urological Association, National Association of Spine Specialists, and Society of Thoracic Surgeons.

Chairman JOHNSON. Thank you very much, Dr. Carius. Ms. Gottlich.

STATEMENT OF VICKI GOTTLICH, ATTORNEY, HEALTHCARE RIGHTS PROJECT, CENTER FOR MEDICARE ADVOCACY, INC.

Ms. GOTTLICH. I am Vicki Gottlich from the Center for Medicare Advocacy. I thank Chairman Johnson, Mr. Stark, and the Members of the Committee for the opportunity to testify before you as the lone representative of beneficiaries in a very long hearing.

I came prepared to discuss the need for a prior determination process using Advance Beneficiary Notices, and the need for a beneficiary ombudsman in HHS. Based on the comments of Mr. Scully and the questions about the appeals process, I rewrote my testimony, because I want to focus on the appeals issues.

Beneficiary representatives across the country do not support CMS's efforts to weaken the appeals protections that were initiated by Mrs. Johnson, Congressman Thomas, and supported in a bipartisan way by this Subcommittee. Those of us who actually represent beneficiaries in the Medicare appeals process know that the problems lie with the contractors and they do not lie with the ALJs, as CMS would have you believe.

Like providers, beneficiaries get inappropriate, conflicting, inaccurate information from contractors. We believe that some of the recommendations made by CMS will only make this provision worse and that they will weaken the role of the ALJ.

The delays at the contractor level are unconscionable. We oppose any effort to extend the time periods from the BIPA time periods. We would like you to know that CMS, in its proposed regulations to implement BIPA, even said that they aren't prepared to enforce the time periods. So, no matter how much extra time you give to

contractors, as CMS requests, CMS isn't going to do anything if the delays continue.

I want to give you two examples that show the problems with contractors that have occurred recently. In response to a request by a paralegal for the laws relied upon in denying a claim for ambulance services, a carrier sent two pages from an OIG report citing fraud and abuse in ambulance claims. An OIG report is not a law upon which a carrier or anyone else may base a decision that care is not medically necessary for an individual.

This example illustrates why both beneficiaries and providers have such problems with early levels of appeals at the carrier and fiscal intermediary stage, and why they have such high success rates at the ALJ hearing level. The ALJs make their decisions based on the laws that govern Medicare, not on OIG reports, other non-legal interpretations, or the confusing and sometimes inaccurate contractor bulletins we see issued and upon which contractors rely in making decisions.

The ALJs are independent, external reviewers who provide beneficiaries with the fair hearing rights required by due process of law. Yet hidden in the budget proposal, CMS is proposing to weaken the ALJ level of review by using alternative mechanisms in lieu of ALJs. These mechanisms will deprive beneficiaries of the first real independent review of the law and facts relating to their claims that they receive.

Moving the ALJs from the Social Security Administration to HHS is opposed by every single beneficiary advocate in this country. We are fearful that ALJs will lose their independence and be beholden to the agency in which they are housed. The ALJs before whom we have appeared in administrative hearings are familiar with Medicare laws and regulations. They understand the legal and Medicare issues and medical issues that are involved.

I want to give you another example that arose yesterday after I submitted my testimony. We received a copy of a confusing and inconsistent fiscal intermediary bulletin that may violate both the CMS skilled nursing facility (SNF) manual, and the Federal court settlement of a case called Sarasatt against Boeing. The SNF provider is using the fiscal intermediary bulletin to try to collect money from the resident beneficiary in violation of the Sarasatt settlement. If we appeal this case, the fiscal intermediary is going to rely on its bulletin, and so it will be a bogus, worthless appeal on behalf of the beneficiary.

At the ALJ hearing, we would be able to submit the law, the SNF manual, and the ALJ would rely on the law and the SNF manual to determine whether or not the beneficiary is entitled to relief. The problem is with the carriers and the fiscal intermediaries that don't rely on real law.

The other problem with the CMS regulations is that they are making it harder for beneficiaries to use the appeals process. Congressman Thomas instituted the BIPA changes because he wanted to make it easier for beneficiaries.

What we see in CMS's proposed regs is a process which would require beneficiaries to have an attorney in order to put together the legal documents and the medical records that CMS would require. Ironically, it would be harder and require more detail to file

an appeal to the ALJ level of review than it is to file an appeal in Federal court.

I want to say one other thing. That is, if you want to save money in the appeals process, eliminate the quick levels of review. Beneficiary representatives believe that the quicks will be another bureaucratic level of review which will hinder their access to care. The quicks will be contractors who are beholden to the entity with whom they contract, and we are concerned that as part of their contract analysis, CMS will look to see how many of the appeals they upheld.

We thank you for the opportunity to testify on behalf of your beneficiary constituents who are not represented adequately on the Regulatory Reform Committee and do not have a stronger voice at CMS or even before Congress as provider organizations. I ask your help in ensuring that regulatory and contractor reform efforts do not undermine the laws this Committee initiated and enacted and court decisions designed to protect beneficiary rights and access to care. Thank you.

[The prepared statement of Ms. Gottlich follows:]

Statement of Vicki Gottlich, Attorney, Healthcare Rights Project, Center for Medicare Advocacy, Inc.

Good afternoon. I am Vicki Gottlich, an attorney with the Healthcare Rights Project of the Center for Medicare Advocacy, Inc. I appreciate the opportunity to address the Subcommittee on Health concerning Medicare regulatory and contractor reform. We, like you, are concerned with the important issue of assuring that Medicare provides older people and people with disabilities basic protection against the cost of medical services.

Using Advance Beneficiary Notices to Establish a Prior Determination Process

One of the few pro-beneficiary provisions included in HR 3391, the Medicare Regulatory Relief and Contracting Bill that passed the House in the 107th Congress, builds upon the use of successful model notices developed by CMS—in this instance the Advance Beneficiary Notices (ABN)—to establish a prior determination process for certain items and services covered by Medicare. We urge you to include this provision in any future legislation, with the modifications discussed below.

Current regulations mandate that ABNs be provided to beneficiaries by physicians who believe that Medicare is likely to deny payment for a particular service. See 42 CFR §§ 411.408(d)(2). The notice serves two purposes: to inform a beneficiary that she may request that the claim for the service be submitted to Medicare for an official determination of Medicare payment, and to inform the beneficiary that she could potentially be liable financially for the service if Medicare denies payment for the claim. If the claim is not submitted to Medicare, and no official decision is received from Medicare, then the beneficiary has no access to the appeals system. In order to appeal a denial of a claim, a beneficiary must both receive the service and have Medicare, rather than the provider, determine that it will not reimburse the provider for the service.

Though the ABN serves as a beneficiary protection, informing the beneficiary of rights and potential responsibility, the ABN also creates barriers to care. Many beneficiaries, fearing that Medicare will not pay for a service, and concerned that they will be unable to pay for the service out of their own pockets, decide to forgo treatment when faced with an ABN. These beneficiaries are relying on the provider's interpretation of Medicare coverage. By forgoing the service, they forgo the right to get an official Medicare determination on whether the claim will be paid, and they lose the right to appeal the unfavorable decision.

Beneficiaries who can afford to pay for the service after receiving an ABN, and who request that the claim be submitted to Medicare, are likely to fair well. Approximately 70% of claims for which an ABN was issued to the patient are paid by Medicare. Thus, beneficiaries who decline a service because they cannot afford to pay are in all probability foregoing a service that would have been covered by Medicare.

Section 408 of HR 3391 creates a remedy for beneficiaries who want a determination from the carrier about whether Medicare will pay for a service for which they received an ABN, but who cannot afford to pay for the service themselves. The process established in that section would allow doctors and patients to request a prior determination from Medicare about whether care will be covered in cases in which an ABN was delivered. The section requires the decision to be made within 45 days of the submission, and allows for a redetermination of an unfavorable prior determination to be issued within 30 days. A beneficiary who receives an unfavorable prior determination may still go through the claims and appeals process after obtaining the service.

What we currently have is a two-tiered Medicare system. Those beneficiaries who receive an ABN and can afford to pay for the services, receive the services, the Medicare claim is filed, and in 70% of cases, Medicare pays the claim. Those beneficiaries who receive an ABN and CANNOT afford to pay for services, do not receive the services, no Medicare claim is filed and they are denied medical care. This provision will rectify this inequity.

While Section 408 creates an important right for beneficiaries, it needs to be strengthened in two ways. First, the 45 day time period for making a determination is too long for some treatments and diagnostic tests. Conditions may worsen while beneficiaries wait for a decision from Medicare. Second, as part of the provider education which plays an important part of regulatory and contractor reform, Medicare contractors should instruct providers on the proper use of ABNs. Beneficiary advocates find that some providers are distributing ABNs routinely for all services, and not just for services in which there is a question about Medicare payment. As a result, beneficiaries are declining care for services for which there is no doubt that Medicare would make a payment.

Medicare Beneficiary Ombudsman

The other beneficiary provision in HR 3391 is Section 303. That section establishes the position of Medicare Beneficiary Ombudsman within the Department of Health and Human Services to assist with complaints, grievances, requests for information, appeals, and disenrollment from Medicare+Choice plans. Currently, there is no central place within HHS or CMS for beneficiaries to go and seek information and assistance. The sources and resources available to beneficiaries are spotty at best. Thus, creation of the Beneficiary Ombudsman would fill a void that is getting increasingly worse.

Much confusion still remains over whether Medicare carriers and fiscal intermediaries have eliminated their beneficiary outreach and education specialist positions. CMS and HHS have recently stated that press reports concerning the elimination of this position are incorrect. Yet individuals who served as outreach and education specialists at carrier and fiscal intermediaries have told beneficiary representatives that they will no longer serve in that capacity. Beneficiary representatives also were told at the February 6, 2003 monthly CMS Advocates Meeting that, because of the cut-backs, carriers would no longer be doing beneficiary outreach about Medicare-covered preventive services at health fairs or providing information about preventive services in consumer newsletters. Although CMS states that beneficiary outreach and education services remain, beneficiary advocates still question the extent to which such assistance will be provided.

The telephone hot-line services also do not provide the kind of assistance that a Beneficiary Ombudsman would provide. They do not assist with appeals, nor are they capable of answering more than the most perfunctory questions. When I asked a representative two weeks ago for the citation to the law upon which she based her response to me, she told me she did not know. When I asked where I could find the law, she told me the Library of Congress. She did not know that the Medicare statute and regulations and CMS policy manuals are all available through the CMS web site.

In order for the Medicare ombudsman to be an effective resource for beneficiaries, the Ombudsman must work closely with State Health Insurance and Assistance Programs (SHIPs). These programs provide the direct, face-to-face assistance that beneficiaries require when working on appeals or trying to decide among Medigap policies, long-term care policies, or Medicare+Choice plans. The Ombudsman should serve to assist the SHIPs in gathering medical records and Medicare policies that are needed to help review a claim or to process an appeal.

Of course, the most effective assistance for beneficiaries would be to fund the existing SHIP programs adequately, and to promote, not undermine, their activities. Again, local SHIPs provide the one-on-one assistance that beneficiaries require in complicated cases. They provide assistance that cannot be provided by a hotline op-

erator with no intimate knowledge of the issues and without the time to spend unraveling a beneficiary's complaint.

One additional point needs to be made. Section 303 would require the Secretary to include only the 1–800 Medicare phone number in the *Medicare & You* handbook. CMS partially implemented this provision by eliminating the phone numbers for the SHIPs but including phone numbers for some of the other contractors. Unfortunately, advocates around the country have found that the 1–800 Medicare hotline cannot effectively assist beneficiaries with more complicated questions than how to get a new Medicare card or how to order publications. The hotlines do not always refer beneficiaries to the SHIP programs, which are the only entities that provide direct, individualized assistance to beneficiaries.

Further, the other Medicare contractors do not consistently provide the correct referrals to beneficiaries who need help, and they often have telephone trees that are daunting to even the most competent of younger, English-speaking adults. For example, I recently called the fraud hotline to report what I considered to be fraudulent activity by an ambulance supplier. The operator told me the issue wasn't fraud against Medicare—though it is surely fraud against the beneficiary—and gave me the phone number of the Durable Medical Equipment Regional Carrier. When I said that DMERCs don't handle ambulance claims, she hung up on me. Medicare beneficiaries and their families deserve correct information and more polite treatment. They deserve an Ombudsman to whom they can turn when they receive the treatment I received.

Other Potential Beneficiary Protections

Congress can and should direct CMS to take other steps to provide beneficiaries with the information they need to get the Medicare-covered care they require.

1. SNF Notices: After hospitalization, Medicare covers up to 100 days of skilled nursing facility (SNF) care. Some times, residents of SNFS are unaware that their Medicare coverage is ending, and they are unaware of the need to secure other means of paying for their nursing home care. CMS should be required to inform residents about the number of days used sufficiently in advance of the end of the 100 days of care. The notices should inform residents about the right to apply for Medicaid and the phone number of the Medicaid office. The notice should also inform residents of the right to appeal if they dispute the calculation of the 100 days.

2. Life-time hospital reserve days: Similarly, beneficiaries who use up their 60 life-time hospital reserve days should receive advance notice informing them that they are depleting their days, that their Medicare coverage is ending, and that they need to find another means of paying for continued hospitalization. Again, the notice should also inform patients of their right to appeal the number of days utilized. Although few beneficiaries ever need such extensive hospitalization, those who do are often unaware that Medicare will stop paying for their care.

3. Hospital discharge information: The Medicare statute requires hospitals to assist patients with discharge planning. As part of this requirement, hospitals should provide a list of Medicare-certified skilled nursing facilities and their financial relations with these facilities. We have heard from advocates around the country that some hospitals discharge patients who would otherwise be eligible for the Medicare-SNF benefit to facilities that are not Medicare-certified without informing them that they would not receive Medicare coverage for their care or that other, Medicare-certified facilities may be available.

4. Medicare+Choice denial notices: Initial determinations and other notices in original Medicare must state the specific reason for the denial, state whether a Medicare policy formed the basis for the denial and explain how to get the policy, and tell beneficiaries how to file an appeal. While current regulations require Medicare+Choice plans to explain the specific reason for the unfavorable determination, few plans state the reasons in a way that is useful to beneficiaries or advocates. Plans should be instructed on providing proper information; CMS should develop model notice language for this use.

Contractor Reform Issues

In 1999 and in 2000, I testified before this subcommittee in support of a bill introduced by then-Subcommittee Chairman Thomas to reduce the time frames by which Medicare contractors, administrative law judges, and the Departmental Appeals Board must issue decisions on Medicare appeals. These important beneficiary protections, along with other appeals reforms, were enacted as Section 521 of the Beneficiary Improvement and Protection Act of 2000.

We appreciate the bi-partisan work of this committee last year to urge CMS to implement Section 521 and ask your assistance again to ward off the efforts by CMS to undermine the protections you enacted for beneficiaries.

The proposed rules to implement Section 521 issued by CMS on November 15, 2002 create loopholes that would allow contractors at all levels of review to avoid compliance with the statutory time frames. 67 Fed. Reg. 69312 (Nov. 15, 2002). CMS in the preamble indicates that it would not take enforcement action against carriers and fiscal intermediaries which fail to meet deadlines. Although Congressman Thomas worked to establish a new appeals system to assist beneficiaries, the CMS proposed regulations would make it almost impossible for a beneficiary to pursue a claim without legal representation. Some of the requirements for appealing to a higher level of review proposed by CMS are more onerous than the requirements for filing a federal court appeal.

We have also learned that CMS is proposing through the budget process to weaken Section 521 protections. They plan to seek legislation to increase time frames for making decisions, without proposing any remedies for beneficiaries when, as now, contractors do not comply.

Most importantly, they are seeking to replace administrative law judges (ALJs) with some other mechanism of review that will not provide the independence and impartiality of ALJs. Beneficiaries rely on ALJs to apply Medicare coverage laws fairly. ALJs look to and interpret the real Medicare law as contained in the statute and regulations in determining whether Medicare should pay for a service. They provide the primary opportunity to obtain a full and honest appraisal of the right to Medicare coverage. We ask your assistance in assuring that the statutory right to a fair hearing before an administrative law judge—a right which stems from basic constitutional right to due process—not be eroded.

Cautions About Regulatory Reform

The Center for Medicare Advocacy and other beneficiary representatives do not agree with the other witnesses who testified today that the voluminous Medicare regulations make it impossible to provide services under the program and impede access to care. Medicare regulations are issued by CMS to implement the changes in the laws passed by Congress, to protect the rights of Medicare beneficiaries to receive medically necessary services, and to assure accountability of providers and of CMS. For example:

- The Balanced Budget Act of 1997 included a specific statutory section, 42 U.S.C. §§ 1395w–26, that directed CMS (a) to establish standards for financial solvency of Medicare+Choice plans, and (b) to establish other standards to carry out the new Medicare Part C, the Medicare+Choice program. Other statutory sections relating to Part C directed CMS to address specific substantive issues, for example, standards for exercising choice and electing a Medicare+Choice plan, guidelines for post-stabilization care, and time periods for appeals of adverse determinations, and included details about what should be included in the regulations. Thus, the approximately 100 pages of regulations added to the Code of Federal Regulations to implement the Medicare+Choice program were done so at the explicit direction of Congress to help with the administration of a new and complex program.
- Federal Medicare and Medicaid rules promulgated by CMS to implement the Nursing Home Reform Law of 1987 have led to reduced use of physical and chemical restraints in many skilled nursing and nursing facilities nationwide, allowing facilities to provide better care for residents at lower cost. They also led to a 30% increase in the use of hearing aids; an increase in the use of toileting programs for incontinent residents; a 28% decrease in the proportion of residents with little or no activity; and a 26% reduction in hospitalizations of residents (resulting in an annual estimated savings to the Medicare program of $2 billion in hospital costs in 1992 dollars). *See*, Dr. Catherine Hawes, *Assuring Nursing Home Quality: The History and Impact of Federal standards in OBRA–1987* (Commonwealth Fund, December 1996).

Medicare regulations and other guidance developed by CMS help assure that beneficiaries receive the services they need and to which they are entitled. Form notices developed by CMS to explain what services have been covered, what services have been denied, why they have been denied, and what a beneficiary can do about a denied service provide accurate information and consistency. Beneficiary vulnerability increases when CMS does not mandate forms or does not include all of the pertinent information in forms.

Advisory Committee on Regulatory Reform

The Center for Medicare Advocacy is one of the many beneficiary organizations that expressed disappointment in the make-up of the Advisory Committee on Regulatory Reform. We believe that the committee was heavily biased against consumers

and did not represent the interests of the many groups for whom the health programs administered by DHHS were intended. A review of committee proceedings shows the effect of this bias. Most of the witnesses who testified before the committee were providers. Many of the recommendations may not have been passed had more beneficiary representatives participated as committee members. Indeed, the proceeding records indicate that most of the votes against committee recommendations were cast by the consumer representatives. We ask that you keep this bias in mind when reviewing the proposed recommendations.

Rather than raise objections anew to committee recommendations in this testimony, I have attached comments filed by the Center for Medicare Advocacy on two controversial issues. The Center disagrees with the recommendations concerning OASIS; OASIS is an important quality assessment tool that should apply to all home health consumers. The Center also disagrees with the recommendations concerning enforcement of nursing home laws; many of the recommendations made by the committee undermine and conflict with the Nursing Home Reform Law.

Although we did not file specific comments on the committee's recommended changes to EMTALA, the Emergency Medical Treatment and Active Labor Act, we are concerned that the recommendations undermine the effectiveness of that provision. EMTALA protects patients by requiring hospitals to screen and stabilize patients in an emergency situation before transferring the patient or asking about insurance coverage. We fear that the recommendations will result in individuals with emergency care needs being turned away from certain locations, just as they were before EMTALA was enacted.

Thank you for the opportunity to testify on behalf of beneficiaries at this hearing.

Chairman JOHNSON. Thank you very much, Ms. Gottlich. I thank the panel for their comments. There are a couple of things that I will follow up on, and then we will move forward.

First of all, Ms. Ryan, I wanted you to go into this issue a little bit more. You mentioned it in the waiver section of your testimony. I believe it was the substance of the last page that you really didn't get to go into as well. The waivers were denied by the Federal Government to test outcome-based measures of quality.

In fact, let's just confine your answer to that, because I would like to know really more about this. Why do you think outcome-based measures are applicable to nursing home care? If they are applicable, why were the waivers denied?

Dr. RYAN. As I understand it, the Medicare waiver authority is more limited than some of the waiver authority under Medicaid in which the States and local communities have been able to look at alternative ways to provide care across separately regulated and paid-for programs.

The State survey process has set standards for the quality of care in nursing homes for purposes of licensure. There are standards that are likewise set that are external for participation in Medicare and Medicaid. Those standards have been external and fairly inflexible in a quickly evolving care setting. Our residents are older, they are more frail, they are suffering co-morbidities. There are many more issues of multiple drugs and a number of things that are part of that care.

Chairman JOHNSON. Can you think of a way to give Members a little clearer understanding why a regulatory system that looks at outcomes is going to work?

Our regulatory system has in the past looked at individual instances; such as: is the bed too high, and all of these little things. In many ways, the outcome does not count. They don't even look at the outcome.

It is hard to grasp this. If you would talk about that?

Dr. RYAN. A patient's overall experience in terms of quality of life and quality of care is impacted by many, many things, many specific instances. If we can identify measures that are valid, measures of both quality of life and quality of care, there ought to be flexibility with regard to the processes that help you achieve that outcome. That is the work that we are trying to do, with the advice of the quality improvement organizations within long-term care under CMS's National Nursing Home Quality Initiative.

How do we begin to grasp the principles of continuous improvement? How do we give persons at the site of care the information that they need to make decisions? Then how do we aggregate that information at the level of the facility and the level of the patient care so we know what their outcomes are?

This is a mindset shift that takes us away from focus on process and structure to one of the individual resident's outcome and the collective outcome at the facility level. This is a paradigm shift for both long-term care and for acute care.

Chairman JOHNSON. It is a paradigm shift. Would anybody else want to comment on that issue? Otherwise, I will go on to Mr. Fay.

Mr. Fay, on the Cost Report, you mentioned that it requires arcane Medicare-specific cost accounting principles. Now, are those different than the cost accounting principles you use across the rest of your patients and for other payors?

Mr. FAY. Yes, ma'am, they are. The accounting principles in use by hospitals, as well as just about every enterprise in this country, are based on generally accepted accounting principles. Medicare has over the years developed Medicare cost reporting principles to recognize costs which are generally lower than total cost.

So, long as we had a cost-based system, those rules were necessary in order to be sure that Medicare paid its claims in accordance with the intent of Congress and the directives of the Administration. As we move away from a cost-based system into a fully prospective system—and I recognize that we still have a few vestiges of cost-based reimbursement left in the system—but once we totally transition to a PPS, it would at least appear to me that we would no longer need a Medicare cost-based system.

Chairman JOHNSON. This has been suggested, and I think it is something we have to look into and discuss more fully. It is expensive to keep different accounting systems up and running.

Mr. FAY. It is. The OMB's conservative estimate is that it takes about 650 hours per year per provider—that includes SNFs and hospitals—to do the Medicare report. We think it is much higher. We have heard for an academic medical center it could be 4,000 hours a year. That is time and energy we would rather see directed towards patient care services.

Chairman JOHNSON. Mr. Stark.

Mr. STARK. Mr. Fay, would you then support a uniform set of accounts and accounting practices for all hospitals?

Mr. FAY. Mr. Stark, personally I would. The committee's recommendation in this regard was to simplify the existing Cost Report, because we recognize that we still had cost-based reimbursement.

Mr. STARK. It is my understanding that the American Hospital Association for years has fought uniform accounting forms, which I would prefer. I would be willing to drop all the government's if we could just have one set; so if we are dealing in Tennessee or Wisconsin or California, all hospitals or all providers are using the same accounting format. Then we could build a database and begin to understand better.

They don't. Each one wants to have their own cost accounting system because they dreamed it up, for whatever reason. They may be valid reasons, but I am suggesting that if your group would be willing to be a little more flexible, I think we could come to an agreement.

I do think it would then require a standardized set of accounting reports. That would be one of the solutions.

Mr. FAY. If I may follow up, sir, the Committee did make that as a long-term recommendation, to go to mandatory, consistent GAP-based reporting formats, whether it is down to a chart or a higher level; but it would still give the Federal Government, and, most importantly, Medicare Payment Advisory Commission access to real-time data that could be used to measure the health of hospitals.

Mr. STARK. Absolutely. I have to think it would help your industry. In other words, although you want to talk about competition all the time, which is okay, but nonetheless, it would seem to me it would be helpful if you could see in a sanitized version what other hospitals were doing. What does the laundry cost per patient in a certain State or a certain area? If you can't pull that information out easily, it is harder for management to make decisions. I hope you would work with us on that.

Dr. Hill, I have the same problem with docs. I don't think if a physician's practice—it is a small percentage—has been identified as having the possibility of over-billing or overcharging, that they can settle. You suggest that it is disruptive to a practice. One would assume we have jackbooted, helmeted people coming into your office and pawing through your medical records and leaving them in a pile on the floor, and I don't think that is really true.

It is not your people. They may have to pull the records out and leave them in a pile someplace. I will tell you, it cannot be any worse than a bank examination or an IRS audit. There are procedures that cause people who have overcharged us—we just had the Federal Bureau of Investigation in my State, and I submit to you it is a lot simpler to just have a random couple of hundred exams.

Again, it would go—and I know your membership is fighting hammer and tongs against standardized patient benefits. Now, someday I think we are going to have to get there. My sense is that the sooner we can get there, the sooner Mr. Luebke can make a fortune selling all the software to do it.

There is a certain independence on the part of your members that doesn't fit very well with having everybody come into a cookie-cutter sort of procedure. I just hope that we can move to it more closely, because if we don't do that we are not going to be able to use all the electronic technology we have, which I think would make all of our lives simpler.

I have to suggest to you that while I have no brief for the government's enforcement as being a lot of fun, that your membership could move us to making it easier, too.

Dr. HILL. I totally agree with that. I think you are behind on what we think now at the AMA about electronic medical records particularly, and standardized procedures and processes.

Our problem is the immediate payment up front before appeals processes are started or completed. That is our only issue. We absolutely would like any overpayment problems or fraudulent problems to be taken care of, but it is just that up-front unfairness we consider in the payment. That is the big issue. Our autonomy as the profession is one of the great things about American medicine, as you well know.

Mr. STARK. I believe it. Dr. Ryan, if I may say, that chart—and again, I hate to be put on the side of encouraging all kinds of regulation. Having just tried to add a bathroom to my house, I can tell you, I understand it.

An awful lot of that up there would be required of an auto dealer or a McDonald's in any city. In other words, all of the State government stuff and the local government stuff and the U.S. Department of Labor stuff and all of the U.S. Department of Transportation, U.S. Department of Justice, all of that is not unique to a medical care provider.

I am sympathetic to people having to fill out forms these days, but I just wanted to suggest that—CMS and this Committee are not responsible for all of those, okay?

Dr. RYAN. Mr. Congressman, I really do understand that. I think one thing which is unique is the degree to which the Justice Department now is regulating the abuse piece and CMS the clinical piece, and we are beginning to see dysfunctional crossover between those two systems.

Mr. STARK. Let me put it this way. At least with the Justice Departmen, as long as you don't become a Muslim and they sock you away without a lawyer, you are in good shape.

Chairman JOHNSON. We only have 12 minutes left. I would like to recognize Mr. McCrery.

Mr. MCCRERY. Thank you, Madam Chair.

Mr. Luebke, you have made an eloquent pitch for the competitive process in contracting. Can you give us some areas or some examples that you think can be done more efficiently in the administrative process, and the magnitude of any savings that might be realized?

Mr. LUEBKE. I am not prepared to talk about magnitude of savings, but I will give some examples. The bill really allows for a specific focus on things like claims processing, so it really can focus on the efficiency of that. In fact, Mr. Scully's testimony also talks about putting some pricing mechanisms in place that really incentivize providers to gain efficiencies and drive down costs. So, I think there are some real opportunities here to drive down costs.

What will happen by focusing on that is it will bring technology, innovation, and commercial best practices, and by applying some of the—like in our case, the very, very highly efficient data centers that—we are continually bringing new innovations, and have al-

most a fanatical focus on how do we drive down costs, how do we bring new innovations and drive down costs per transaction.

Some specific examples from the past of some things we have done: We do the processing for the claims for the State of Missouri for Medicaid. We have worked with them to significantly drive down the number of medical claims processed, to automate and have electronic claims processing, and streamline the process by bringing Internet technologies so the providers can easily enter their transactions via the Internet.

We have brought point-of-service capabilities for pharmacy claims so the pharmacies can again enter the claims very, very easily, but, even more importantly, can see in real time whether the person wanting to get the prescription—whether they are eligible or not. So, you get real-time availability of information.

During the period of time we have done that, we have more than doubled the number of claims, but we have reduced the absolute number of people who are doing it; so at least a doubling of the efficiency of it, and some other important things. We have reduced the time for payment from an average of 12 days to payment down to 2 days, so there are some very, very significant improvements.

Mr. MCCRERY. While you don't have any estimated magnitude of savings, you are convinced savings are possible through these kinds of efficiencies?

Mr. LUEBKE. That is something that I really have not studied in terms of looking at specifically what could we drive as a result of this. That would be something that would take some more detailed study.

Mr. MCCRERY. Mr. Fay, just quickly, you recommend that EMTALA not apply for hospital in-patients that are transferred or sent home in an unstable condition. What conditions are there in existing procedures that would guard against the patient—or the care deteriorating?

Mr. FAY. Yes, sir. The way I understand it, under the current Medicare participation for a hospital, including various State rules and so forth, once a patient is in the hospital you have an obligation, a separate obligation and a stronger obligation, to treat the patient; either stabilize the patient or transfer the patient if needed.

We think those in-patient obligations actually exceed EMTALA, and we are afraid if we have both obligations, EMTALA and the existing in-patient requirement, you are going to have a layering of regulations which could conflict and could cause problems and confusion among doctors, patients, and hospitals.

Mr. MCCRERY. So, you think without EMTALA there is sufficient direction under the law to make sure that the patient is stable?

Mr. FAY. Yes, I do.

Mr. MCCRERY. Dr. Hill, you testified that the AMA continues to hear from physicians about onerous audits and overpayment demands. I know that is true because I hear from my physicians.

Will the provisions in the bill that we are considering solve those problems, or do you think there are some more things that we could put in the bill to provide more relief?

Dr. HILL. We are very pleased with the provisions of the bill. If they are implemented, and monitored so we know they are implemented, we think it would solve a problem. We thought that last year and we still think that. We think that would correct the problem greatly. The only other issue would be the appeals process, which also I think would improve.

Mr. MCCRERY. Thank you, Madam Chair.

Chairman JOHNSON. Thank you very much. I thank the panel. We do have a vote, and Members were not able to come back, so we will conclude our hearing. I do want you to know two things. First of all, I appreciate the quality of your testimony.

Ms. Gottlich, one thing that you could help us look at is what are the ways that we can prevent so many cases from coming into the system. That seems to be the Administrators' real problem is how does he manage this volume.

There have to be ways we can reduce that volume. One of them seems to be that at the initial level not to have the carrier have the first hearing, since they are already biased. That struck me as absolutely bizarre that was the case. I have seen problems with that over the years. We need to look at whether there are ways we can change it that will have volume impact so we will be able to meet those time frames.

I also would not underestimate the impact on patients and quality that some of these system changes can have. Just the technology example you gave and speediness of response and payment is important, particularly for small providers.

I do want you all to think about what else could be recommended if the task force were to continue, and what, of the business it did not get to, should it be focusing on; what are the data issues?

Many of you said we have the same steps in OASIS and MDS and the hospital, it is dumb to be re-collecting. We know that. Be thinking about ways we could improve the performance, better integrate the system, because we certainly have the technology capability to do that. Unless we start doing it, we will never also improve quality.

Thank you very much for being here today. We appreciate this good start.

[Whereupon, at 2:27 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of AdvaMed

AdvaMed is pleased to provide this testimony on behalf of our member companies and the patients and health care systems we serve around the world. AdvaMed is the largest medical technology trade association in the world, representing more than 1100 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $71 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the $169 billion purchased annually around the world.

AdvaMed would like to thank Chairwoman Johnson, Ranking Member Stark, and the members of the Subcommittee for their bipartisan effort to make the Medicare program more efficient and effective for providers and Medicare beneficiaries. Medicare is a critical program for some 41 million Americans, and we greatly appreciate the way that the Committee reached out to the health care community last Congress to develop legislation to make the program easier to understand, comply with, and participate in.

In his State of the Union Address in January, the President described our health care system as the model of skill and innovation for the world. The President noted

that the pace of discovery in advanced health care and preventive care in our country is "adding good years to our lives" and "transforming" health care.

We believe it is in the best interest of patients and the Medicare program to have the Medicare system capitalize on advanced technologies, which have revolutionized the U.S. economy and driven productivity to new heights and new possibilities in many other sectors. Significant advances in health care technologies—from health information systems that monitor patient treatment data to innovative diagnostics tests that detect diseases early and lifesaving implantable devices—improve the productivity of the health care system itself and vastly improve the quality of the health care delivered. New technologies can reduce medical errors, make the system more efficient and effective by catching diseases earlier—when they are easier and less expensive to treat, allowing procedures to be done in less expensive settings, and reducing hospital lengths of stays and rehabilitation times.

Our concern, however, is that Medicare is often too slow to incorporate technologies and methods of delivering care. We appreciate the Committee's past efforts to address these problems legislatively because unnecessary time delays frustrate the program's ability to provide the most cost-effective, high-quality care to America's seniors and individuals with disabilities.

Congressional Efforts to Improve Medicare Beneficiary Access to Technology

AdvaMed applauds Congress for the steps it took in the Balanced Budget Refinement Act of 1999 (BBRA) and the Benefits Improvement and Protection Act (BIPA) of 2000 to begin to make the Medicare coverage, coding and payment systems more effective and efficient. In addition, the Centers for Medicare and Medicaid Services (CMS) has recently made some changes to modernize its coverage and payment systems.

Despite these efforts, however, current policies still fail to keep up with the pace of new medical technology. Serious delays continue to plague Medicare in its efforts to make new medical technologies and procedures available to beneficiaries in all treatment settings.

As demonstrated by a Lewin Group report provided by AdvaMed to the Congress in 2000, Medicare delays can total from 15 months to five years or more because of the program's complex, bureaucratic procedures for adopting new technologies. Keep in mind that all this is after the two to six years it takes to develop a product and the year or more it takes to go through the Food and Drug Administration (FDA) review. In addition, the impact of the delays is even more pronounced when you consider that the average life cycle of a new technology can be 18 months.

These delays stem from the fact that for a new technology to become fully available to Medicare patients, it must go through three separate review processes to obtain coverage, and receive a billing code and payment level. Serious delays in all three of these areas create significant barriers to patient access.

Last Congress, AdvaMed strongly supported provisions based on language from the Medicare Innovation Responsiveness Act (MIRA) introduced by Representative Ramstad (R-MN) and incorporated in HR 2768, the Medicare Regulatory and Contracting Reform Act, that would have created a council for technology and innovation within CMS to oversee and coordinate Medicare coverage, coding and payment decisions on new technologies and require the General Accoutning Office to report on ways CMS can make better use of external sources of data to expedite hospital inpatient payment updates. We request that the Committee include them again in legislation it crafts this year.

Improving the Reimbursement Process for New Clinical Laboratory Tests

Innovative diagnostic tests help save lives and reduce health care costs by detecting diseases earlier when they are more treatable. With today's advanced technology, testing can be performed in a variety of settings from large clinical reference laboratories to hospital outpatient labs, to physician offices, and even in patient's nursing homes.

Although BIPA substantially improved the processes for setting reimbursement rates for advanced diagnostic tests, serious flaws still exist, making it difficult for beneficiaries to gain access to many innovative technologies. That's why AdvaMed strongly supports H.R. 569, the Medicare Patient Access to Preventive and Diagnostic Tests Act recently introduced by Reps. Dunn (R–WA), McDermott (D–WA) and Ramstad. Provisions from this bill were incorporated in H.R. 2768 last Congress to establish much needed procedures and criteria for determining reimbursement for new clinical laboratory tests. We are hopeful that similar provisions will be included again, along with additional provisions from H.R. 569.

Maintaining the Local Coverage Process under Contractor Reforms

While some reforms to the contracting process are warranted, AdvaMed strongly believes that reforms should not result in changes in local carriers or consolidated jurisdiction for carriers should maintain a process for making coverage decisions locally, and for securing input from the local medical community.

AdvaMed strongly supports Medicare's local coverage process as a vital route for timely patient access to the vast majority of innovative medical technologies. The local coverage process offers an important alternative to national coverage decision-making by the Centers for Medicare and Medicaid Services (CMS), which runs Medicare and oversees local contractors. Currently, the Medicare national process causes delays of 15 months to five years or more for patients who need access to technologies that are subject to a national review.

Consolidation of the number of local Medicare contractors that make coverage decisions would severely constrict or eliminate the local coverage process and create significant new delays in patient access to important new medical technologies and services. AdvaMed appreciates the work of Congress and CMS to examine Medicare contractor operations in areas such as accountability and performance incentives. However, as Congress addresses this issue, we urge it to avoid steps that would undermine the local coverage process as a route to early patient access to new medical technologies.

The local coverage process provides the flexibility and timeliness needed to keep pace with rapid advances in medical technology. Current flexibility at the local level very efficiently incorporates the majority of new procedures and technologies into the existing Medicare payment systems. This flexibility includes timely access to local contractor decision-makers; an active relationship with the local medical community and understanding of local medical practice, and the ability to make case-by-case determinations. Local decision-making authority provides Medicare beneficiaries access to new procedures and technologies without having to wait until these innovations have been disseminated nationally.

A report by the Lewin Group, a prominent health care policy research firm, also highlighted the value of the current local Medicare coverage process. According to the Lewin Group, "the local coverage process remains a critical avenue for obtaining coverage." In fact, only about 12 services per year are reviewed through a national coverage process.

Preservation of the local coverage process is particularly important, the Lewin Group found, because it offers a way for patients to gain access to many innovative technologies that otherwise would encounter significant coverage delays at the national (CMS) level. Lewin cites the example of a breakthrough technology in women's health, dual x-ray absiorptiometry, which is used to diagnose osteoporosis. It took Medicare more than seven years to cover this technology at the national level. However, coverage decisions by local Medicare contractors during that time enabled many women to gain access to this technology who otherwise would not have been able to receive it.

AdvaMed strongly believes that, despite any contracting reforms, a process for making coverage decisions locally, and for securing input from the local medical community (through local coverage advisory committees) should be maintained. We strongly support provisions that will be included in the Medicare Innovation Responsiveness Act of 2003, which will soon be reintroduced this Congress by Rep. Ramstad, that would:

- Require contractors to designate at least one individual to serve as a medical director for every two states (or portions thereof) to perform local medical review functions;
- Require the continuance of local carrier advisory committees (CACs) in each state to ensure that local medical review policy reflects the consensus of the local physician community. Changes in local coverage decisions should be subjected to the normal review and comment process with the local CAC.
- To address the need for rapid creation of codes for emerging technologies, require CMS to establish a process for automatically issuing national temporary codes in response to requests from local Medicare contractors. Timely assignment of national codes is more critical than ever to patient access with the recent elimination of the "local codes" that were used by Medicare contractors.

Additional Steps to Improve Patient Access to Technology

Congress and CMS already have told America's Medicare beneficiaries that they will make key reforms to expand access to promising medical technologies in clinical trials, provide a meaningful opportunity to appeal claims denials, and reduce bar-

riers to innovative medical technologies in the hospital inpatient setting. Unfortunately, none of these reforms have been meaningfully implemented.

That's why AdvaMed also supports the following provisions that will be included in the Ramstad bill, the Medicare Innovation Responsiveness Act of 2003, that will:

- Set 6–12 month deadlines for Medicare to implement coverage, coding and payment for new medical technologies subject to a national coverage decision;
- Direct CMS to provide reimbursement for the routine costs of care for breakthrough medical technologies for Medicare beneficiaries. Current Medicare policy is impeding developing of potentially life-saving technologies like heart assist devices because it does not provide reimbursement of routine costs of care during clinical trials. While CMS issued a memo two-and-a-half years ago announcing its intention to implement a presidential executive order to provide reimbursement for the routine costs of care for these technologies, the Agency has not yet finalized the policy. This policy would have a minimal impact on Medicare spending (as breakthroughs represent only six percent of FDA-approved studies) but a huge impact on Medicare patients awaiting emerging breakthroughs like implantable artificial hearts, bioartificial livers and kidneys and "bionic eyes" to treat blindness;
- Ensure that Medicare appeals rulings apply to similar cases. Congress passed legislation to require CMS to address the problem, but Medicare patients remain caught in an appeals system that is badly broken. Delays that often stretch longer than a year and many seniors and people with disabilities effectively are denied the ability to appeal claims that are denied by Medicare;
- Require Medicare to accept and consider valid external data on resources associated with new medical technologies to reduce delays in providing adequate reimbursement for these innovations and update codes on a quarterly basis; and
- Build on the provisions in BIPA to reduce the current two or more year delays in updating inpatient reimbursement rates to reflect changes in medical technology. BIPA established special transitional payments for new medical technologies used in the inpatient setting. However, CMS implemented this legislation so narrowly it failed to fulfill Congressional intent. In fact, only one new medical technology has qualified for the temporary payments. Last year, the House passed legislation to ensure that, whenever possible, new technologies are placed into existing inpatient payment categories (DRGs) that provide payment levels that cover average costs of care that most closely approximate the cost of care using the new technology. If no appropriate DRG exists, Medicare should provide a temporary additional payment to cover the costs of a new technology. The Ramstad bill repeats the House-passed language of last year, and we support its inclusion in a bill crafted by the Committee again this year.
- Require that CMS exercise its Inherent Reasonableness authority in a more open, transparent, and fair process, both nationally and regionally, including a notice of intent to conduct an IR study, and publication of the results. DMERCs should be required to follow the national process. An appeals mechanism for IR determinations should be established that is similar to the mechanism available for appealing a national coverage determination.

Conclusion

AdvaMed thanks the Subcommittee members again for their collaborative efforts to improve and strengthen the Medicare program. We look forward to working with this Committee, the Congress and the Administration on this important legislation again this Congress, as well as additional ways to improve the quality of care available to seniors through Medicare and foster the delivery of innovative therapies for patients.

Statement of the Alliance to Improve Medicare

The Alliance to Improve Medicare (AIM) is pleased to submit this statement for the hearing record to the Ways & Means Subcommittee on Health. We applaud the Subcommittee's continued attention to the issue of reforming burdensome Medicare regulations.

Medicare regulatory burdens adversely affect both beneficiaries and providers. AIM believes that the current rigid and outdated Medicare benefit structure and bureaucracy must be replaced. Program administrators must be provided with the

flexibility to make new health care innovations and technologies more readily accessible to Medicare beneficiaries. Medicare administrators have recently taken solid steps to reduce excessive program complexity and bureaucracy caused by the more than 110,000 pages of federal rules, regulations, guidelines and mandates but more can be done to streamline current Medicare requirements on both beneficiaries and providers.

"The Medicare Regulatory and Contracting Reform Bill"

AIM applauds the bipartisan efforts of Subcommittee Chairwoman Nancy Johnson and Ranking Member Pete Stark to develop this important legislation. While we have not yet reviewed the final text of the legislation introduced today, AIM members support efforts to create a more collaborative relationship between CMS and the providers who serve Medicare beneficiaries, to address provider concerns, and to improve beneficiary and provider education.

Similar legislation was approved twice in the 107th Congress, once by unanimous vote and again as part of the "Medicare Modernization and Prescription Drug Act of 2002." That legislation sought to extend important regulatory relief to health care providers and to modernize Medicare's contracting processes. The 107th legislation also sought to consolidate promulgation of CMS regulations and to create specific time frames for progression of new regulations. AIM members support these provisions and look forward to working with the Subcommittee on this legislation in the 108th Congress.

HHS Activities

HHS Secretary Tommy Thompson established the Secretary's Advisory Committee on Regulatory Reform in 2001 to examine the regulatory burdens placed on beneficiaries and providers in the Medicare program. The Committee held a series of meetings across the country to receive comments and recommendations from consumers and providers on ways to streamline regulatory requirements and lessen regulatory burden within the Medicare program. The Advisory Committee's final report, released in November 2002, represents an excellent step toward improving the Medicare program for both health care providers and beneficiaries.

The Committee's final report contained over 250 recommendations to reduce obstacles to care, reduce paperwork requirements, improve communications, and expand the use of technology to ensure quality care. Specifically, the Advisory Committee considered and adopted many of the reform recommendations submitted by AIM including reducing extensive data collection requirements and providing better information on beneficiary eligibility and covered services.

AIM is especially pleased that Secretary Thompson announced the creation of an "internal strike force" to continue the work of the Committee and to review and implement many of the Advisory Committee's remaining recommendations. To date, HHS has already implemented more than two dozen recommendations contained in the Advisory Committee's final report. AIM members will continue to work with the HHS staff to recommend and comment on efforts to further reduce regulatory burdens on beneficiaries and providers. Specifically, we hope HHS will consider ways to further improve the timely availability of advanced medical technologies through better coordination between CMS, FDA, and technology innovators. Further, HHS should adopt and implement the Advisory Committee's recommendations to ensure consistent communications between the CMS central office and the regional offices, particularly with regard to beneficiary education materials. Finally, AIM members will work with HHS to further reduce extensive data collection efforts.

Key Principles for Improving Medicare

AIM is the only organization focused solely on fundamental, bipartisan modernization of the Medicare program to ensure that senior citizens have more health care coverage choices, better benefits (including prescription drug benefits), and access to the latest in innovative medical practices, treatments and technologies. AIM coalition members include organizations representing seniors, hospitals, small and large employers, insurance plans and providers, doctors, medical researchers and innovators, and others.

AIM's key principles to improve and strengthen Medicare address both the administration of the Medicare program and the benefits provided to program beneficiaries. Most importantly, AIM believes prescription drug benefits should be offered to all Medicare beneficiaries as an integral part of Medicare health coverage. AIM members believe any new drug benefit should be added as part of comprehensive, market-based improvement efforts, including efforts to streamline and reduce regulatory burdens.

AIM also seeks to ensure the long-term financial integrity and solvency of the Medicare program. The program's existing financial and structural systems must be

strengthened to ensure adequate long-term financial stability to meet the challenges presented by the retirement of the baby boom generation and the projected doubling of the Medicare population.

Additionally, AIM believes Congress and the Administration must address the financial crisis facing health plans and providers. Ensuring access and choice for senior citizens should be a primary goal of the Medicare program but both are threatened by inadequate provider reimbursements. Health plans have left the Medicare+Choice program and some providers have stopped accepting new Medicare patients because the program's reimbursement rates are inadequate to cover even the costs of basic care.

AIM supports increased consumer choice in health care coverage options and believes that all Medicare beneficiaries should have the option to choose from a range of coverage options similar to those available to Members of Congress, federal employees and retirees, and millions of working Americans under 65 years of age who are covered by private plans. Unfortunately, excessive regulation and inadequate reimbursement of private sector providers participating in Medicare+Choice have seriously constrained coverage areas.

Finally, AIM supports improvement of health care coverage through better coordination of care including health promotion and disease prevention efforts. The traditional Medicare program has not kept pace with private sector benefits and plans offering preventive health care and screening measures such as annual physicals, hearing and vision tests, and dental care. Medicare beneficiaries, more so than other population age groups, can benefit from these preventive measures which can help reduce long-term costs and ensure appropriate, early treatment of health problems.

Conclusion

Complexity in Medicare's rules governing beneficiary and provider participation has resulted in increasingly bipartisan support to improve the fairness of the system for all participants. AIM applauds Subcommittee Chairwoman Nancy Johnson and ranking member Pete Stark for their bipartisan efforts in the discussion of necessary regulatory reforms to the Medicare program.

AIM appreciates the opportunity to provide these comments to the Health Subcommittee and applauds the Subcommittee's work toward improving Medicare. AIM urges the Subcommittee to consider sensible, long-term solutions to the problems confronted by the Medicare program and by Medicare beneficiaries and we urge Members to work together on a bipartisan basis to achieve comprehensive Medicare reform. We look forward to working with the Subcommittee and other members to further reduce Medicare regulatory burdens and complexity.

Statement of the American Association for Homecare, Alexandria, Virginia

The American Association for Homecare (AAHomecare) would like to take this opportunity to thank the Ways and Means Health Subcommittee, Chairwoman Johnson, and Ranking Member Stark for their continued involvement in Medicare Regulatory Reform. AAHomecare is a national association whose members represents a continuum of home healthcare including suppliers of durable medical equipment (DME), orthotics and prosthetics, home health agencies (HHAs) and suppliers of re/hab and assistive technology. As a representative of both DME suppliers and HHAs, AAHomecare supports the Subcommittee's effort to improve the regulatory, appeals and contracting processes under the Medicare Program. However, we would like to take this opportunity to express some of our concerns regarding specific provisions in H.R. 3391, which we believe may affect a provider's or supplier's due process rights.

CORRECTION OF MINOR ERRORS AND OMISSIONS

H.R. 3391 establishes a process for correcting minor errors and omissions on claims without requiring the provider or supplier to go through the expense of an appeals process. Currently, most claims are denied because the claims failed to comply with one or two technical requirements. For instance, a provider or supplier may have failed to secure the physician's signature on all verbal orders prior to billing, or may have failed to include any minor treatment changes. These omissions or errors are easily correctible, but because supplier or provider are required to appeal claims, payment can be delayed for up to a year. This can put a substantial amount of financial stress on a provider or supplier and can severely interfere with their capacity to continue their business operation.

AAHomecare strongly supports the Subcommittee's position that providers and suppliers should not have to undergo an appeal simply because of a minor error or omission. By allowing them to correct discrepancies in claims submitted to a carrier, without an appeal, the Subcommittee is ensuring a more efficient and cost-effective Medicare system. Furthermore, this provision is a useful tool in ensuring, not only that a provider or supplier will not undergo economic hardship, but also that a beneficiary will have continued access to services. We urge that any regulatory reform should include a provision such as this for correction of minor errors and omission.

NEW EVIDENCE AND ALJ HEARINGS

While we are supportive of the general intent behind the regulatory reform provisions of H.R. 3391, we are extremely concerned by Section 403(a)(3). Under Section 403(a)(3) a supplier or provider may not introduce evidence in an appeal that was not presented at the reconsideration hearing conducted by the Qualified Independent Contractor (QIC), unless there is good cause which precluded the admittance of such evidence before or during reconsideration.

The Centers for Medicare and Medicaid Services (CMS) are adopting a similar stance to the one potentially created by Section 403(a)(3). On November 15, 2002, CMS issued its proposal for the implementation of BIPA, which included a provision that would severely curtail evidence presented by a supplier or provider during an ALJ hearing. Specifically, the proposed rule 405.1019 states submission of any new evidence that was not presented to the QIC must be accompanied by a written statement. Under this proposed rule the statement must explain why the evidence was not previously submitted to the QIC, and the ALJ can only admit the evidence if good cause exists.

Both Section 403(a)(3) and the CMS proposed Section 405.1019 significantly restrict the opportunity a provider or supplier has to offer additional and new evidence during a ALJ hearing, in effect requiring a full and early presentation of evidence at the QIC level. CMS has based this proposed regulation, on its long held belief that a high reversal rate on appeals is due to the presentation of new evidence at the ALJ level. While it is true that many claims have been reversed at the ALJ level, the decisions to reverse denials are not arbitrary but rather are founded on the new evidence substantiating a provider's contention that the overpayments is unfounded.

Furthermore, a provider's and supplier's right to introduce new evidence should be safeguarded by any regulatory reform. Often, the ALJ will reverse a denial based on evidence that was unavailable to the interest party during the QIC review.

For example, the probe sample data and methodology used by the carrier is not available to a supplier or provider before the ALJ hearing. A supplier or provider will have to request the probe sampling methodology from the carrier after the reconsideration decisions has been rendered. Therefore, the interested party does not have immediate access to this information from the carrier, but must wait for the information to be turned over. Once the interested party received the information, he or she would need to consult with experts and expend a significant amount of resources to review the sample methodology after receiving it, so as to determine whether the contractor's sample lacks statistical weight or whether the methodology used was erroneous.

We strongly urge this Committee to make sure that any regulatory reform allows providers and suppliers to introduce evidence of erroneous sampling techniques during an ALJ hearing. Many cases that reaches the ALJ have been reversed after the interested party presented evidence showing that the sampling methodology was biased or that a sample was incorrectly taken. In order to maintain due process and ensure fairness, a provider or supplier should be allowed to introduce this type of evidence.

Currently, providers and suppliers can provide live testimony and may introduce new evidence during an ALJ hearing. They are not required to provide good cause or submit a statement by explaining why the information was not included. In fact, the ALJs have come to rely on provider and supplier testimony as an aid when deciding whether the interested party did have a reasonable basis to believe that the claim would be covered. This has helped to ensure fairness and due process during appeals. Both H.R. 3391 and 67 CFR 405.1019 would prohibit live testimony that has repeatedly helped exemplify why the contractors denial was incorrect.

In on case, the fiscal intermediary has denied $20,000 in home health claims representing an entire year of services for a patient who suffered from Multiple Sclerosis (MS). The reason given for the denial was that the patient's physician had not prescribed the commonly used medicine for MS. The denial stated that the drug Athcar was not identified by the Physicians Desk Reference for treatment of MS, despite other references that list it as an alternative. In this case the physician had

prescribed it as an alterative because the patient could not afford the commonly prescribed Interferon. At the ALJ level, the HHA introduced evidence from the treating physician and relied on other authoritative reference to show why the Athcar had been used instead of Interferon. The physician was also able to show how the alternate medication had been effective. Based on this testimony, the ALJ was able to reverse the denial.

Conversely, H.R. 3391 and 67 CFR 405.1012 would allow contractors to present any additional evidence, change the basis of their denial of the claims and present additional testimony that they believe is pertinent. Under both H.R. 3391 and CMS' proposed rule, contractors would be required to provide the ALJ with any additional information requested by the ALJ, so as to aid it in understanding the contractor's position and helping it formulate its decision. Allowing contractor's to testify and present new evidence during the appeals process while denying the same opportunity to an interested party would severely go against due process and fairness. In essence, this would severely undermine the position of suppliers and providers because they would not be allowed to present evidence to contradict the contractor's new arguments, and would not be allowed to adapt their position to reflect contractor changes in arguments during an appeal.

AAHomecare urges the Subcommittee to establish a standard that does not limit the type of information presented during an ALJ hearing. We recommend that any regulatory reform should allow suppliers and providers to present testimony of a treating physician opinions, expert opinions, and provider and supplier testimony, as necessary, to the ALJ. Furthermore, a supplier or provider should be allowed to present evidence which was previously not available, or which at the time was not relevant to the claim set forth by the contractor. It is important to ensure that regulatory reform legislation should distinguish between new evidence that involves readily available clinical documentation from the provider or supplier from other Medicare evidence such as expert opinion, clarifying treating physician opinions and documentary evidence from providers or suppliers that are not directly involved in a disputed claim, if due process is to be maintained.

LIMITED USE OF EXTRAPOLATION

The use of extrapolation can often lead to significant problems for both DME suppliers and HHAs. Often the sampling methodology used during extrapolation lacks any semblance of statistical validity, which in turn can result in a significant expenditure of resources by providers and suppliers. Furthermore, the use of extrapolation often results in the drastically inflated overpayment. This large inflation will force many providers and suppliers to pay hundreds of thousands of dollars, and forces some into bankruptcy.

In one instance, the ALJ ruled in favor of an HHA after throwing out the denials as well as finding the extrapolation and the sampling methodology used by the physical intermediary as erroneous. While the HHA received a favorable verdict, it had suffered irreparable harm, leading to its bankruptcy even before the decision was rendered. This case is of particular concern, given that the home health agency was the only provider in that area for medically complex home health patients.

Currently, the Durable Medical Equipment Regional Carriers (DMERCs) also use extrapolation in determining overpayments. Not unlike HHAs, DMEs are faced with inflated overpayments that are based on erroneous sampling methodology. However, what is particularly disturbing is that the DMERCs use extrapolation and base their denials on rules that have not come into effect at the time the service was rendered. For these reasons, AAHomecare strongly urges that the use of extrapolation and sampling methodology should be curtailed.

AAHomecare believes that H.R. 3391 addresses many of the concerns shared both by HHAs and DME suppliers. We support limiting the circumstances in which a Medicare contractor can request a provider or supplier to produce records or supporting documentations, to those two circumstances delineated in Section 405(f)(3):

1. where either there is a sustained high level of payment error, or
2. where documented education intervention has failed in correcting the payment error.

Despite the limited use created by Section 405(f)(4), there is still a great room for Medicare contractors to interpret Section 405 which may lead to unjustified used of extrapolation. Therefore, AAHomecare urges that the Subcommittee clearly define the phrase "high level of payment error." The Subcommittee needs to provide contractors with guidance (preferably a detailed written guidelines within this bill) as to what constitutes a high payment error. If this term is not defined, the contractor could apply his own subjective definition of "high level of payment error." By clearly defining what constitutes a "high level of payment error" the Subcommittee can pre-

vent the inconsistent application of extrapolation by different Medicare contractors, as well as by the same contractor when reviewing different health supplier or provider claims.

We would further urge the Subcommittee to add a provision that would state that any payment errors will not be deemed to exist where the provider can show that there exists some basis in the law to support the claim as submitted. In this instance, we feel that it is important create a sense of security amongst providers and suppliers, that they can in fact rely on existing laws and regulations when submitting a claim. We strongly believe that a supplier or provider should not be required to second guess the law, nor be penalized for submitting claims based on a reasonable interpretation of law. Under such a provision, the Medicare contractor would be allowed to deny individual claims, but the provider or supplier could rely on law relied on when appealing.

REGULATORY REFORM SHOULD NOT INCLUDE CONSENT SETTLEMENTS

Section 405(f)(5) of H.R. 3391 grants to the Secretary the power to settle a projected payment with a provider or supplier by the use of a consent settlement. Before offering a consent settlement, the Secretary is required to inform the suppliers or providers of the contractors finding of overpayment. The supplier or provider is then given the opportunity to either accept the consent settlement or undergo statistical valid random sampling.

Routinely, Medicare contractors have used consent settlement agreements to strong arm a provider into waiving their right to appeal, despite their honest and usually well-founded belief that the denial was an error. Often, a home health provider will settle its claims with the contractor, not because it supports the contractor's finding, but rather because of the costs they will incur if they fail to accept. Providers and suppliers who do not settle will be forced to incur greater costs associated with appealing the decision as illustrated in the example below.

In one post payment audit, the fiscal intermediary denied 56% of a sample of claims submitted by one small HHA. This percentage was extrapolated to a $65,000 overpayment. In this case, the provider refused to accept a consent settlement agreement and appealed all claims to the ALJ. The ALJ in turn reversed over 95% of the denials. Although, the HHA did receive a favorable outcome, it incurred substantial costs associated with the appeal over the four years that it took from the time of denial to the time of reversal.

If a provider or supplier chooses not to accept a proffered settlement, then the contractor may apply the Statistically Valid Random Sample (SVRS). An SVRS examines a larger number of claims, usually consisting of 200–400 claims. Such an investigation by its very nature is largely disruptive to the operation of home health agencies and DME providers, and may force the business to cease all business activity. Therefore, it is not surprising that many providers and suppliers feel the need to settle, despite their honest belief that the initial probe sample findings where inaccurate because of the exorbitant costs associated with SVRS.

AAHomecare urges the Subcommittee to reconsider including consent settlements in H.R. 3391 or any other regulatory reform legislation. While the Subcommittee has addressed at least one problem associated with consent settlements, i.e. limiting the use of extrapolation, we believe that the detrimental effects associated with consent agreements outweigh any potential benefits. If the Subcommittee allows the use consent settlements, it will unwittingly provide contractors with a tool by which it may strong-arm service providers into settling, even if consent settlements are used only in a fraction of reviewed claims. Those providers who challenge, the sampling methodology may be forced into economic hardship associated with a SVRS or a lengthy appeal. The Subcommittee may unwittingly place the provider or supplier in a position in which it can no longer provide any services. This is of particular concern where the home health provider or DME supplier provide a specialized type of service in an area.

AAHomecare further recommends that if the Subcommittee decides to include consent settlements in H.R. 3391, it should create a provision that allows a provider to settle, while still maintaining the right to appeal the sample probe methodology used by the provider. A provider or supplier should be allowed to appeal the probe method without undergoing an SVRS, otherwise they may be subjected to unjust financial burdens.

DEFFERING RECOUPMENT DURING APPEAL

H.R. 3391 prohibits any recoupment of overpayment until the conclusion of the reconsideration hearing. We applaud this Subcommittee's continued effort to create an insulating mechanism to protect providers from wrongful payment recoveries.

Currently, providers and suppliers are required to make payment before going forth in their appeals process, causing many of these companies to undergo substantial financial hardship for a claim where an error exists in the overpayment determination.

While AAHomecare agrees that the Secretary should not be allowed to recoup overpayments until the conclusion of a reconsideration hearing, we believe that this Subcommittee should further extend this provision by limiting recovery until the claim has run its full course throughout the appeals process and a final and binding decision has been rendered. As Tom Scully testified last year, physicians, providers and suppliers should have the same rights taxpayers enjoy. A taxpayer who is audited has the right to withhold payment, as long as interest accrues, while an appeal is pending. Both suppliers and providers should be entitled to the same right throughout their entire appeal process. Instead, HHAs and DME suppliers are required to pay the amount after the reconsideration hearing, not allowing the party to avail himself of the benefits of an ALJ hearing.

AAHomecare fully appreciates that a substantial controversy exists concerning further delaying recoupment beyond reconsideration. However, we base this recommendation on two well-founded premises. First, recoupment of an extrapolated amount often results in eliminating an opportunity for a provider or supplier to seek an appeal. If a provider or supplier is forced to make payment of potentially hundreds of thousands of dollars, they will undergo a severe financial burden if they continue to incur the cost associated with an appeal. Second, it is administratively difficult to recompute the amount of the extrapolated overpayment after each level of appeal where some of the sample claims are usually reversed.

We also recommend that any extrapolation should be dropped if the provider or supplier obtains a reversal of 10% or more of the sample claim denial on appeal. In such a case, the sample denials would seem to not be a statistically valid representation of denied claims in the universe of claims. If the overpayment represents more than 10% of the provider or supplier revenue, we believe that the interested party should be able to repay the amount during a three year period. By this means, the Subcommittee could ensure that companies will not suffer financial hardship that will cause the HHA or DME supplier to either cut back on the services it provider or file for bankruptcy.

AAHomecare would further recommend that an additional provision be added to H.R. 3391. We believe that the Subcommittee should establish a provision that would protect home health providers where overpayment relates to an error in the administration of benefits by Medicare itself. HHAs are susceptible to unknown amounts of liability due to Medicare's own inability to appropriately process Medicare home health PPS claim. A year ago, CMS determined that its system failed to make the payment adjustment when a patient was admitted to another home health agency or readmitted to the same agency within 60 days of discharge.

AAHomecare recommends that the Subcommittee include legislation that would limit the ability of CMS to institute retroactive payment adjustments on any claims to more than one year previous. Financial integrity cannot be maintained by a provider or services who is required to carry on a indeterminate amount of financial liability from one year to the next.

OASIS:

As of December 2002, CMS have instituted changes aimed at decreasing the burdens associated with the collection of information under the Outcome and Assessment Information Set (OASIS). CMS eliminated two OASIS collection time point and seventeen data items. Thirteen of the seventeen data items consist of demographic information, which have been moved to the tracking sheet and should be completed by agency office staff.

AAHomecare supports the implication of OASIS and the reduction of paperwork. AAHomecare recommends that certain policy changes should be incorporated as soon as possible. We believe that the Subcommittee should also instruct the secretary to request CMS to lengthen the definition of "in patient stay" from 24 hours to 72 hours. We also feel that it is important to instruct the CMS to widen the recertification window from 5 day to at least 10 days to ensure greater flexibility among for an agency to schedule assessment during the patient scheduled visits. Lastly, we urge the Subcommittee to instruct the Secretary take steps to make OASIS electronic program specification and the risk adjustment methodology readily available to the public and allow the public to submit comments on any program specification changes.

GUIDANCE BY SECRETARY OR AGENT:

We strongly support limiting any sanctions on providers or suppliers if they reasonably rely on the guidance of Section 102(c) of H.R. 3391. Providers and suppliers should not be subject to repayment of amounts that they received in reasonable reliance on the guidance from the Secretary or an agent of the Secretary.

CONCLUSION:

We appreciate this opportunity to express our concerns and present our suggestions to the Subcommittee. We greatly value your continued effort on these matters. AAHomecare strongly believes that there is much at stake in regulatory reform, and recommend that any legislation adopted should maintain due process and fairness. H.R. 3391 is a good starting point for Medicare appeal and regulatory reform. We hope that these comments and suggestions are helpful and look forward to working with you to pass a regulatory reform legislation that will further the objective of efficiency and fairness.

Statement of the American Association of Health Plans

AAHP COMMENDS HOUSE WAYS AND MEANS SUBCOMMITTEE FOR ADVANCING REGULATORY REFORMS

The American Association of Health Plans (AAHP) and our member plans are pleased to have had the opportunity to contribute to the important work of the Secretary of Health and Human Services' (HHS) Advisory Committee on Regulatory Reform. Last year, we were pleased to contribute to the Advisory Committee's work on several fronts:

- Two health plan representatives served as members of the Advisory Committee: Heidi Margulis, senior vice president for government relations of Humana; and Leonard Schaeffer, chairman and CEO of Wellpoint Health Networks.
- In March 2002, AAHP submitted comments to the Advisory Committee outlining proposed solutions for reducing regulatory burdens associated with Medicare, Medicaid, and the privacy and administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA).
- In March 2002, four AAHP member plans testified before the Advisory Committee regarding opportunities for improving the administration of the Medicare+Choice program. The health plans that testified were Blue Shield of California, Group Health Cooperative, PacifiCare Health Systems, and Sun Health.

AAHP and our member plans applaud Secretary Thompson for his strong commitment to improving the administration of HHS programs on behalf of health care consumers. At his direction, the Advisory Committee outlined more than 250 recommendations for streamlining HHS regulatory requirements in its November 2002 report. This report lays a foundation for concrete changes that will reduce unnecessarily burdensome and duplicative regulations while at the same time making HHS rules more effective in promoting high quality care for consumers.

The steps HHS has taken in recent months to implement the Advisory Committee's recommendations are clear evidence of the department's commitment to simplifying federal regulations and maintaining accountability in order to better serve consumers. We look forward to working with HHS as it continues to implement reforms designed to restore common sense to the regulatory system by striking a balance between the vital goals of efficiency and accountability. The Advisory Committee's recommendations represent an important starting point in that effort.

Statement of the Honorable Ronald G. Bernoski, President, Association of Administrative Law Judges, Milwaukee, Wisconsin

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to submit this statement. My name is Ronald G. Bernoski. I am an Administrative Law Judge ("ALJ") who has been hearing Social

Security disability cases at the Office of Hearings and Appeals ("OHA") of the Social Security Administration ("SSA") in Milwaukee, Wisconsin, for over 20 years.

This statement is presented in my capacity as the President of the Association of Administrative Law Judges ("AALJ"), which represents the ALJs employed in the SSA OHA and the Department of Health and Human Services ("DHHS"). One of the stated purposes of the AALJ is to promote and preserve full due process hearings in compliance with the Administrative Procedure Act for those individuals who seek adjudication of program entitlement disputes under the Social Security Act.

We strongly oppose the Medicare Appeals item in the 2004 President's Budget that would authorize the Secretary of the DHHS to "use alternate mechanisms in lieu of Administrative Law Judge review" for processing Medicare appeals under Title XVIII of the Social Security Act. This budget item is a stealth attack on the American public's due process rights to an appellate administrative hearing and decision by an ALJ appointed pursuant to the Administrative Procedure Act ("APA") after a denial of Medicare benefits by the DHHS Centers for Medicare & Medicaid Services ("CMS"). These due process rights are provided by the Social Security Act and the APA.

The CMS Administrator, Honorable Thomas Scully, said that "[t]he President's FY2004 budget includes provisions to implement Medicare appeals reform," when he testified before the Subcommittee on Health of the House Committee on Ways and Means at the February 13 Hearing on Medicare Regulatory and Contracting Reform. He also testified that CMS is "proceeding toward the transfer to CMS of the Medicare hearing function currently performed by the Administrative Law Judges (ALJ) in the Social Security Administration (SSA). We have already had extensive discussions with SSA to explore administratively transferring the Medicare hearing function to CMS."

However, the CMS Administrator did not inform the Subcommittee that the Medicare Appeals item buried in the 2004 President's Budget would permit CMS to strip away the Medicare beneficiaries' and providers' due process rights under the Social Security Act and APA to a hearing and decision on appeal before an APA ALJ. The CMS Administrator also did not tell the Subcommittee that, on October 22, 2002, he signed an agreement with the Connecticut Department of Social Services to test a two-step non-APA Medicare administrative appeals process that provides a review of an appealed Intermediary's reconsidered determination by an unspecified CMS official followed by a private sector arbitration as the final administrative step. CMS' reliance upon 42 U.S.C. § 1395b–1, which authorizes the DHHS to conduct "demonstration projects" to test cost saving techniques in specified processes, as authority to test a change in the appellate process is questionable. There also is a question whether it is lawful for the federal government to permit private binding arbitration to supplant federal sovereignty by privately resolving disputes involving rights to public benefits without access to the due process of law and equal protection in a public forum.

The proposed regulations recently published by the CMS entitled "Changes to the Medicare Claims Appeal Procedures" include a note that the Medicare appeals function now performed by SSA ALJs is expected to be transferred back to HHS by October 1 of this year. Proposed regulations are published by federal agencies pursuant to the APA to inform the public in advance of agencies' contemplated actions. However, nothing is said to the public in the proposed Medicare regulations promulgated by CMS Administrator Scully that suggests CMS is contemplating a non-APA ALJ appeals process for Medicare beneficiaries and providers. 67 FR 69182 (November 15, 2002).

Any plan to deny Medicare beneficiaries and service providers the right to a full due process hearing under the APA before an ALJ will result in a denial of basic procedural due process rights to the American people. Without APA due process, Medicare beneficiaries and service providers would have no recourse to an independent decisionmaker during the administrative process.

If CMS is permitted to take these steps over 60 years backward from procedural due process, hundreds of thousands of Americans who appeal from denials of Medicare benefits under the Social Security Act will find themselves left with a process that undermines administrative fairness and the public's confidence in that fairness. Our citizens and lawful permanent residents deserve to keep their well-established right to full due process before an independent decisionmaker.

The APA was adopted by Congress in 1946 to ensure that the American people were provided hearings that are not prejudiced by undue agency influence. The securing of fair and competent hearing adjudicators was viewed as the heart of the APA. The APA presently is codified at 5 U.S.C. §§ 551–559, 701–706, 1305, 3105, 3344, 4301(2)(E), 5335(a)(B), 5372, and 7521.

The APA was enacted to achieve reasonable uniformity and fairness of the federal administrative process for members of the American public with claims pending before federal agencies. The APA sets forth a due process administrative procedure for the hearing and decision by ALJs of cases brought before the federal agencies to which the APA applies. The APA provides the minimum standards for federal administrative due process in the Executive Branch, and delineates procedures for adjudicative administrative proceedings, namely individual case decisions about rights or liabilities as an agency's judicial function. This includes uniform standards for the conduct of adjudicatory proceedings including the merit appointment of ALJs.

By APA mandate, the ALJ is an independent, impartial adjudicator in the administrative process and there is a separation of the adjudicative and prosecutorial functions of an agency. The ALJ is the only impartial, independent adjudicator available to a claimant for benefits in the federal administrative process, and the only person who stands between the claimant and the whim of agency bias and policy. If CMS ends the APA process for Medicare appeals and returns to using subordinated employees who would decide benefits appeals as an instrument and mouthpiece for CMS, we will have returned to the days when the agency was both prosecutor and judge.

The decisionmaking independence provided by the APA is not for the benefit of the ALJ but instead is provided for the protection of the American people. The protections are intended to ensure that the American people receive a full and fair due process hearing with a decision based on the evidence in the hearing record without agency pressure.

The Supreme Court recently reaffirmed the applicability of the APA to federal administrative adjudications, "the numerous common features shared by administrative adjudications and judicial proceedings," "the similarities between the role of an ALJ and that of a trial judge," and the importance of the APA structure that ensures the ALJs' independence of agency influence in deciding cases. *Federal Maritime Commission v. South Carolina State Ports Authority*, 535 U.S. 743, 122 S. Ct. 1864, 1872–1873 (2002). In *FMC*, the Supreme Court relied upon its language in *Butz v. Economou*, 438 U.S. 478, 513–514 (1978), which is stated here directly from *Butz*:

[F]ederal administrative law requires that agency adjudication contain many of the same safeguards as are available in the judicial process. . . . They are conducted before a trier of fact insulated from political influence. See [5 U.S.C. § 554(d)]. A party is entitled to present his case by oral or documentary evidence [5 U.S.C. § 556 (d)], and the transcript of testimony and exhibits together with the pleadings constitute the exclusive record for decision. [5 U.S.C. § 556(e)]. The parties are entitled to know the findings and conclusions on all of the issues of fact, law, or discretion presented on the record. [5 U.S.C. § 557(c)].

There can be little doubt that the role of the modern federal hearing examiner or administrative law judge within this framework is "functionally comparable" to that of a judge. His powers are often, if not generally, comparable to those of a trial judge: He may issue subpoenas, rule on proffers of evidence, regulate the course of the hearing, and make or recommend decisions. See [5 U.S.C. § 556(c)]. More importantly, the process of agency adjudication is currently structured so as to assure that the hearing examiner exercises his independent judgment on the evidence before him, free from pressures by the parties or other officials within the agency.

In *Butz*, the Supreme Court elaborated upon the reasons that Congress enacted the APA's many protections to assure the decisional independence of ALJs and enumerated those protections. 438 U.S. at 513–514:

> Prior to the Administrative Procedure Act, there was considerable concern that persons hearing administrative cases at the trial level could not exercise independent judgment because they were required to perform prosecutorial and investigative functions as well as their judicial work, see, *e.g., Wong Yang Sung* v. *McGrath*, 339 U.S. 33, 36–41 (1950), and because they were often subordinate to executive officials within the agency, see *Ramspeck* v. *Federal Trial Examiners Conference*, 345 U.S. 128, 131 (1953). Since the securing of fair and competent hearing personnel was viewed as "the heart of formal administrative adjudication," Final Report of the Attorney General's Committee on Administrative Procedure 46 (1941), the Administrative Procedure Act contains a number of provisions designed to guarantee the independence of hearing examiners. They may not perform duties inconsistent with their duties as hearing examiners. 5 U.S.C. § 3105 (1976 ed.). When conducting a hearing under § 5 of the APA, 5 U.S.C. § 554 (1976 ed.), a hearing examiner is not responsible to, or subject to the supervision or direction of, employees or agents engaged in the performance of

investigative or prosecution functions for the agency. 5 U. S. C. § 554(d)(2) (1976 ed.). Nor may a hearing examiner consult any person or party, including other agency officials, concerning a fact at issue in the hearing, unless on notice and opportunity for all parties to participate. [5 U.S.C. § 554 (d)(1)]. Hearing examiners must be assigned to cases in rotation so far as is practicable. [5 U.S.C. § 3105]. They may be removed only for good cause established and determined by the Civil Service Commission [now OPM] after a hearing on the record. [5 U.S.C. § 7521]. Their pay is also controlled by the Civil Service Commission. [5 U.S.C. § 5372].

There is a close relationship between the APA and the Social Security Act. The Supreme Court has stated that the APA "is modeled upon the Social Security Act." *Richardson v. Perales*, 402 U.S. 389, 409 (1971).

It is clear that Congress intended the APA to apply to adjudications conducted under the Social Security Act, including Medicare adjudications. That the APA applies to the Social Security Act hearing process is stated extensively in *Adjudications by Administrative Law Judges Pursuant to the Social Security Act also Are Adjudications Pursuant to the Administrative Procedure Act*, Robin J. Arzt, 22–2 J. NAALJ _____ (Fall 2002), and *Are You Willing to Make the Commitment in Writing? The APA, ALJs, and SSA*, Jeffrey Scott Wolfe, 55 Okla. L. Rev. 203 (Summer 2002).

The Medicare program (the "Medicare Act"), which provides federally funded hospital and supplementary medical insurance for elderly and disabled people, was established in 1965 as Title XVIII of the Social Security Act. 42 U.S.C.§§ 1395–1395ggg, as amended. The Medicare Act provides, in pertinent part, that an individual who is "dissatisfied with any determination under [42 U.S.C. § 1395ff(a)] as to [entitlement to Medicare Part A or Part B benefits]. . ., shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 205(b) [42 USCS § 405(b) of Social Security Act Title II]. . . ." 42 U.S.C. § 1395ff(b)(1).

Accordingly, if Social Security Act Title II adjudications are APA adjudications, then the APA necessarily also applies to Medicare adjudications. The first part of Social Security Act Title II, which provided for old age and survivors insurance benefits, was enacted in 1935. Social Security Act of 1935, 49 Stat. 620, 627 (1935). A claimant's right to a hearing in the event of a denial of his claim for old age and survivors insurance benefits first was created by the 1939 amendments to the Act. A denied reconsideration entitled a claimant to a hearing, Pub. L. No. 76–379, 53 Stat. 1360 (1939): "Upon request by [an applicant for benefits or certain relatives of the applicant] . . . who makes a showing in writing that his or her rights may be prejudiced by any decision the Commissioner of Social Security has rendered, the Commissioner shall give such applicant and such other individual reasonable notice and opportunity for a hearing with respect to such decision." 42 U.S.C. § 405(b). This is the only Social Security Act hearing process that existed at the time that the APA was enacted.

In the *Attorney General's Manual on the Administrative Procedure Act* (the "Manual"), which is part of the APA legislative history, the Attorney General expressly and unequivocally stated that the determinations of claims under Title II of the Social Security Act are adjudications covered by the APA: *"[T]he residual definition of "adjudication" in section 2(d) was intended to include such proceedings as the following: . . . [t]he determination of . . . claims under Title II (Old Age and Survivor's Insurance) of the Social Security Act. . . ."* U.S. Justice Dept., *Attorney General's Manual on the Administrative Procedure Act* 14–15 (1947) (emphasis added), *citing*, Senate Judiciary Committee Hearings on the APA (1941) at 657, 1298, 1451 *and* S. Rep. No. 752 at 39; 92 Cong. Rec. 5648.

According to the Supreme Court, the Manual is an important part of the legislative history of the APA. The Manual is "a contemporaneous interpretation" of the APA, *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519, 546 (1978), that has been "'given some deference by [the Supreme] Court because of the role played by the Department of Justice in drafting the legislation, and Justice [Tom C.] Clark was Attorney General both when the APA was passed and when the Manual was published.'" *Steadman v. SEC*, 450 U.S. 91, 102, n. 22 (1981), *quoting*, *Vermont*, 435 U.S. at 546. "In prior cases, [the Supreme Court has] given some weight to the Attorney General's Manual on the Administrative Procedure Act (1947), since the Justice Department was heavily involved in the legislative process that resulted in the Act's enactment in 1946." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302, n. 31 (1979), *citing*, Vermont, *supra*. Justice Scalia has described the Manual as "the Government's own most authoritative interpretation of the APA. . . . That document . . . was originally issued 'as a guide to the agencies in adjusting their procedures to the requirements of the Act.'" *Bowen v. George-*

town University Hospital, 488 U.S. 204, 218 (1988) (*concurring op.*), *quoting*, Manual, p. 6, and *citing*, *Steadman, Chrysler* and *Vermont*.

Therefore, Social Security Act Title II old age and survivors insurance benefits program adjudications are APA adjudications.

The Supreme Court implicitly held in *Bowen v. Georgetown University Hospital* that the APA generally applies to the Medicare Act when it expressly affirmed the decision by the U.S. Court of Appeals for the District of Columbia that both the APA and the Medicare Act barred the Secretary of Health and Human Services from issuing a rule that retroactively sets new cost-limits for Medicare payments for health services: "The [circuit] court based its holding on the alternate grounds that the APA, as a general matter, forbids retroactive rulemaking, and that the Medicare Act, by its specific terms, bars retroactive cost-limit rules. We . . . now affirm." *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988), *affirming*, 821 F.2d 750 (D.C. Cir. 1987). The Supreme Court did not discuss the APA further because it found that the Secretary's retroactive cost-limit rule was invalid on the threshold issue of whether the Medicare Act permitted retroactive rulemaking. *Id*. at 208, 215–216.

In 1976, Congress expressly ended what it described as the confusion during the preceding few years regarding the applicability of the APA to the parts of the Social Security Act enacted after the APA by enacting Public Law No. 94–202, which is entitled "An Act to amend the Social Security Act to expedite the holding of hearings under titles II, XVI and XVIII by establishing uniform review procedures, and for other purposes." Pub. L. No. 94–202, 89 Stat. 1135–1137 (1976). Congress enacted Public Law No. 94–202 in connection with the SSI program to reiterate that it intends the APA to apply to all adjudications of Social Security Act claims that have been denied by the SSA. The provisions of *"[Public Law No. 94–202] clearly placed all social security cases (OASDI, SSI, and medicare) under the APA*." Conversion of Temporary Administration Law Judges, H.R. Doc. No. 617, 95th Cong., 1st Sess. 4–5 (1977) (emphasis added).

Therefore, Congress expressly intended that the APA apply to the Medicare administrative adjudication process, just the same as Congress intended for Title II and all other Social Security Act adjudications.

In addition, since the APA applies to Medicare adjudications, the enactment of the 2004 President's Budget item that would authorize the use of a non-APA ALJ hearing process for Medicare appeals is not sufficient to override the APA requirements. The APA provides that a "[s]ubsequent statute may not be held to supercede or modify [the APA], except to the extent that it does so expressly." 5 U.S.C. § 559. The Supreme Court repeatedly has held that "[e]xemptions from the terms of the Administrative Procedure Act are not lightly to be presumed in view of the statement in § 12 of the Act [now codified at 5 U.S.C. § 559] that modifications must be express . . ." *Marcello v. Bonds*, 349 U.S. 302, 310 (1955), *citing*, *Shaughnessy v. Pedreiro*, 349 U.S. 48, 51 (1955) (The APA "is to be given a 'hospitable' interpretation."). *Ardestani v. INS*, 502 U.S. 129, 134 (1991); *Brownell v. Shung*, 352 U.S. 180, 185 (1956). An exemption from the APA will not be found unless the subsequent statute expressly supercedes the provisions of the APA and/or the Congressional intent to override the APA or any of its provisions is sufficiently clear to overcome the presumption that the APA applies. *Id*. The legislative intent of Congress is clear: "Subsequent legislation is not to modify the bill except as it may do so expressly." Senate Judiciary Committee Report on the APA, S. Rep. No. 752, 79th Cong., 1st Sess. 29 (1945); H.R. Rep. No. 1980, 79th Cong., 2nd Sess. 47 (1946).

Finally, in a letter dated January 9, 2001, SSA Commissioner Kenneth S. Apfel affirmed the relationship between the APA and the Social Security Act for Social Security hearings:

> The Social Security Administration (SSA) has a long tradition, since the beginning of the Social Security programs during the 1930s, of providing the full measure of due process for people who apply for or who receive Social Security benefits. An individual who is dissatisfied with the determination that SSA has made with respect to his or her claim for benefits has a right to request a hearing before an Administrative Law Judge, an independent decisionmaker who makes a *de novo* decision with respect to the individual's claim for benefits. As the Supreme Court has recognized, SSA's procedures for handling claims in which a hearing has been requested served as a model for the Administrative Procedure Act (APA). Congress passed the APA in 1946 in part to establish uniform standards for certain adjudicatory proceedings in Federal agencies, in order to ensure that individuals receive a fair hearing on their claims before an independent decisionmaker. SSA always has supported the APA and is proud that the SSA

hearing process has become the model under which all Federal agencies that hold hearings subject to the APA operate. SSA's hearing process provides the protections set-forth in the APA, and SSA's Administrative Law Judges are appointed in compliance with the provisions of the APA.

Any retreat by CMS from SSA's long and proud tradition by which SSA conducts Medicare hearings will have a substantial adverse effect on Medicare beneficiaries and providers and will deny them basic due process rights. American citizens will have fewer procedural due process rights than they had prior to the enactment of the APA.

We urge you to protect the due process rights of the American people by continuing to provide Medicare beneficiaries and providers the full range of rights to an appellate administrative due process hearing and decision by an APA ALJ under both the APA and the Social Security Act. APA due process offers the best protection to our citizens in their dealings with the federal government.

Most Americans first see the face of the United States government when they seek Social Security Act benefits. How people view that face depends upon the quality of justice they receive. The current hearing procedure provided by the Social Security Act and APA allows for high quality due process and a sense of fair play. Full APA due process must be preserved in Medicare cases for the benefit of our citizens.

Statement of the Emergency Department Practice Management Association, McLean, Virginia

On behalf of the Emergency Department Practice Management Association (EDPMA), we would like to thank Chairman Johnson and Ranking Member Stark for their hard work on Medicare regulatory reform. We appreciate the opportunity to present this written statement about Medicare issues that affect EDPMA members. We would be happy to work with you on this important topic.

Background

EDPMA represents emergency department (ED) medical groups, ED billing companies, consultants, and vendors who support ED medical groups. EDPMA members provide patient care and ED management services to approximately 25% of the estimated over 100 million emergency department patients in the U.S. EDPMA supports regulatory reform to the Medicare program. EDPMA submitted comments to the Department of Health and Human Services (HHS) on March 5, 2002 (see attached). We have highlighted our main concerns below. While we are pleased by the recommendations of the Secretary of HHS' Regulatory Reform Task Force, and progress made by HHS to date, we also believe that there are several areas where additional reforms are necessary.

CMS' Reassignment Policies

Many hospitals in the U.S. contract with outside medical groups to provide physician services in their EDs. Unlike private payors, CMS policy does not currently allow ED medical groups that use independent contractors to obtain a Medicare group enrollment number. However, CMS has recognized that many physician independent contractors are needed to staff EDs and established a compliance scenario (the "lockbox" arrangement) to permit these physicians to continue to provide services to Medicare beneficiaries and stay affiliated with the ED medical group.

The current compliance scenarios create a process that is labor-intensive, expensive, and actually decreases the integrity of the Medicare program as multiple individual provider numbers are created and the program has a more difficult time spotting billing trends or flagging any questionable practices that might be common to physicians affiliated with the same group. In contrast, if the medical group could obtain a number, there would be a direct relationship between the group and the Medicare program, thereby enhancing program accountability.

EDPMA believes that CMS should permit ED medical groups to enroll with the Medicare program and receive direct payments for physician services whether those services are rendered by employees or independent contractors. We urge Congress to include in any regulatory reform measures a provision to explicitly permit ED medical groups to enroll with the Medicare program and receive direct payment for physician services whether those services are rendered by employees or independent contractors.

855 Enrollment Forms

As noted above, EDPMA believes that ED medical groups should be able to enroll with the Medicare program and receive direct payments for physician services whether those services are rendered by employees or independent contractors. In addition to this policy concern, EDPMA also supports other changes to the enrollment process. We believe the enrollment form (the "855") and the process used by the CMS contractors in reviewing the applications could be streamlined. EDPMA continues to emphasize the importance of Internet-based electronic provider enrollment, and EDPMA has detailed its reasons supporting the creation of such an Internet-based enrollment process in previous written comments filed with CMS. Congress passed an electronic signature law and many state laws support electronic signature and verification. EDPMA strongly believes now more than ever that an Internet-based enrollment process could save both CMS and the provider community millions of dollars over what is today almost entirely a paper-based system for provider/supplier enrollment.

EDPMA also recommends continued refinement to the 855 form to make it user-friendly. EDPMA urges the Committee to take steps to ensure that enrollment applications are processed fairly, consistently, and in a timely fashion. Providers should be able to complete and submit the applications electronically and to check on the status of the applications electronically.

EDPMA is also concerned that the contractors are not held to a tough standard regarding the processing time. Under the current process, EDPMA is concerned that the majority of enrollment delays do not result in discovery of an applicant who is not eligible to participate in the Medicare program. Rather, the delays are often due to mere contractor inaction and/or inefficiency, and the provider gets its enrollment number, albeit much delayed. ED physicians must see all patients due to the federal EMTALA requirements. They do not have the option of not seeing Medicare patients while they await their number. Therefore, the amount of Medicare payments postponed by the delay in issuance of numbers is not insignificant.

EDPMA suggests that CMS continue to modify the 855 forms to make them straightforward, establish electronic filing, and coordinate the filing of the 855 with the filing of EDI, and EFT agreements.

EMTALA

EDPMA members have many concerns related to the effect of the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. §1395dd, (EMTALA) on hospitals and emergency physicians. EDPMA supports the formation of an EMTALA industry advisory group as EDPMA is concerned that HHS' current interpretation of EMTALA has extended beyond the law's initial intention to prevent patients from being refused treatment or inappropriately transferred. Two general problems have many implications. First, requiring hospitals to provide services without a corresponding requirement for payment leads to an unstable and untenable financial situation for hospitals and for physicians. Second, the divergence between legal and medical definitions of key EMTALA terms (e.g., "stable") has led to much confusion in the field as to appropriate practices. We support comments made by the American College of Emergency Physicians (ACEP) to the Committee on this matter as well.

Documentation Guidelines for Evaluation and Management Services

It is EDPMA's understanding that CMS is currently working with the American Medical Association (AMA) to revise the Documentation Guidelines ("DGs") for physician evaluation and management services. In the past, EDPMA has provided a number of comments in this area. In general, EDPMA supports the use by CMS of DGs so that CMS can verify that objective standards were provided before paying claims. We believe the 1995 documentation guidelines are a good example of objective standards. EDPMA also believes that physician use of appropriately structured DGs promotes quality care for all patients, including Medicare beneficiaries. EDPMA supports the use of objective criteria to avoid confusion for physicians and their coders. CMS should work closely with providers in making sure that any DGs are workable from the provider's perspective.

Once again, EDPMA appreciates this opportunity to provide input to the Committee. We would be happy to provide additional materials in any of the areas noted above.

Christy Schmidt
Executive Coordinator, Regulatory Reform Initiative
Office of the Assistant Secretary for Planning and Evaluation

Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Schmidt:

EDPMA submits these comments to the Secretary's Advisory Committee on Regulatory Reform (the Committee) in response to the January 4, 2002 request for public input set forth in the Federal Register, 67 Fed. Reg. 599. EDPMA represents emergency department (ED) medical groups, ED billing companies, consultants, and vendors who support ED medical groups. EDPMA members provide patient care and ED management services to approximately 25% of the estimated over 100 million emergency department patients in the U.S. EDPMA supports the efforts by the Department of Health and Human Services (HHS) to reduce regulatory burdens imposed by HHS regulations, and we look forward to working with the Committee in this area.

EMTALA

EDPMA members have many concerns related to the effect of the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd, (EMTALA) on hospitals and emergency physicians. EDPMA supports the formation of an EMTALA industry advisory group as EDPMA is concerned that HHS' current interpretation of EMTALA has extended beyond the law's initial intention to prevent patients from being refused treatment or inappropriately transferred. Two general problems have many implications. First, requiring hospitals to provide services without a corresponding requirement for payment leads to an unstable and untenable financial situation for hospitals and for physicians. Second, the divergence between legal and medical definitions of key EMTALA terms (e.g., "stable") has led to much confusion in the field as to appropriate practices.

EDPMA believes the statute's requirements have been inappropriately extended through regulations, the interpretive guidelines and the enforcement policies of state surveyors, CMS, and the HHS Office of Inspector General (OIG). Most recently, HHS expanded the reach of EMTALA to non-ED settings through the requirements for provider-based entities. The application of EMTALA in these settings is outside the scope of the statute, and we believe applying these requirements to non-ED settings may tax the already thin resources of many hospital Eds. CMS has stated that it intends to re-examine the provider-based EMTALA requirements. EDPMA applauds this decision and urges CMS to expeditiously revisit these regulations, and other important EMTALA issues.

General review of current EMTALA policies is necessary as the EMTALA regulations, the interpretive guidelines, and the positions of state surveyors are often extremely complicated and confusing. Two OIG reports issued in January 2001 highlighted the confusion that surrounds implementation of the EMTALA regulations and the inconsistency in application and enforcement of EMTALA among the CMS regions. A particular area of confusion relates to the responsibility of hospitals to provide "on-call" physicians. In many communities, specialist physicians are refusing to be on-call, and hospital EDs are concerned that patient care could suffer.

Recommendations: EMTALA's regulatory scope should be modified to be consistent with the statute. CMS should establish a technical advisory group, as both the OIG and General Accounting Office (GAO) recommended last year. CMS should also seek to ensure that the Medicare and Medicaid programs pay for medical screening examinations and stabilizing treatment for all patients who are treated pursuant to the EMTALA mandate.

2002 Medicare Physician Fee Schedule

The 2002 Medicare physician fee schedule included cuts of approximately 8% to emergency physicians. While the negative update affects most physicians, the cut particularly affects emergency physicians as emergency medicine was already facing cuts in the practice expense/work values. This Medicare cut comes at a time when many emergency physicians are experiencing more than 20% annual premium increases in the costs of medical malpractice insurance. Unlike other physicians who can decide whether or not to participate in Medicare, emergency physicians are compelled under EMTALA to see all patients who present to the emergency department.

Recommendations: EDPMA recognizes that CMS faced statutory limitations in calculating the update. However, EDPMA believes CMS could make changes within the current statutory framework to reflect some of the particular expenses borne by emergency physicians providing the nation's safety net. Specifically, EDPMA believes CMS should recognize the high level of uncompensated care provided in the ED and the standby costs.

CMS' Reassignment Policies

Many hospitals in the U.S. contract with outside medical groups to provide physician services in their EDs. Unlike private payors, CMS policy does not currently allow ED medical groups that use independent contractors to obtain a Medicare group number. However, CMS has recognized that many physician independent contractors are needed to staff EDs and establish a compliance scenario (the "lockbox" arrangement) to permit these physicians to continue to provide services to Medicare beneficiaries and stay affiliated with the ED medical group.

The current compliance scenarios create a process that is labor-intensive, expensive, and actually decreases the integrity of the Medicare program as multiple individual provider numbers are created and the program has a more difficult time spotting billing trends or flagging any questionable practices that might be common to physicians affiliated with the same group. In contrast, if the medical group could obtain a number, there would be a direct relationship between the group and the Medicare program, thereby enhancing program accountability.

Recommendations: CMS should permit ED medical groups to enroll with the Medicare program and receive direct payments for physician services whether those services are rendered by employees or independent contractors. CMS can modify its enrollment procedures to permit group enrollment by providing guidance to the Medicare contractors in written instructions and/or by adding an appropriate exception to the Medicare Carriers Manual. EDPMA believes this policy change can be effected without statutory or regulatory change, and in fact, CMS has done so in the past. In 1999, CMS added a reassignment exception to the Medicare Carriers Manual for faculty practice plans without a statutory or regulatory modification. Implementation of a new group enrollment process could include important safeguards for the Medicare program. Possible safeguards include assumption of group responsibility for any overpayments.

855 Enrollment Forms

As noted above, EDPMA believes that ED medical groups should be able to enroll with the Medicare program and receive direct payments for physician services whether those services are rendered by employees or independent contractors. In addition to this policy concern, EDPMA has concerns with the 855 enrollment forms currently in use by CMS and its carriers. The new forms went into effect on November 1, 2001, with a transition period until January 1, 2002. EDPMA applauds CMS on its approach to fine-tuning these forms by reaching out to the affected community for comments. EDPMA believes, however, that a number of concerns remain.

The 855 forms and the process used by the CMS contractors in reviewing the applications remain cumbersome, confusing, and require multiple manual submission of documents. In addition, the current approach results in significant delays in receipt of Medicare enrollment numbers. EDPMA continues to emphasize the importance of Internet-based electronic provider enrollment, and EDPMA has detailed its reasons supporting the creation of such an Internet-based enrollment process in previous written comments filed with CMS. Congress passed an electronic signature law and many state laws support electronic signature and verification. EDPMA strongly believes now more than ever that an Internet-based enrollment process could save both CMS and the provider community millions of dollars over what is today almost entirely a paper-based system for provider/supplier enrollment.

EDPMA also recommends continued refinement to the 855 form to make it user-friendly. EDPMA urges the Committee to take steps to ensure that enrollment applications are processed fairly, consistently, and in a timely fashion. Providers should be able to complete and submit the applications electronically and to check on the status of the applications electronically.

EDPMA is also concerned that the contractors are not held to a tough standard regarding the processing time. EDPMA members frequently receive last-minute requests for supporting documentations. Often, the matter could have been resolved by a phone call as soon as the question came up. Instead, contractors often send out a form requesting additional information that does not clearly identify the cause for regarding the earlier submitted documentation as inadequate. Under the current process, EDPMA is concerned that the majority of enrollment delays do not result in discovery of an applicant who is not eligible to participate in the Medicare program. Rather, the delays are often due to mere contractor inaction and/or inefficiency, and the provider gets its enrollment number, albeit much delayed. ED physicians must see all patients due to the federal EMTALA requirements. They do not have the option of not seeing Medicare patients while they await their number. Therefore, the amount of Medicare payments postponed by the delay in issuance of numbers is not insignificant.

Recommendations: EDPMA suggests that CMS continue to modify the 855 forms to make them straightforward, establish electronic filing, and coordinate the filing of the 855 with the filing of EDI, and EFT agreements.

Documentation Guidelines for Evaluation and Management Services

It is EDPMA's understanding that CMS is currently revising the Documentation Guidelines ("DGs") for physician evaluation and management services. In the past, EDPMA has provided a number of comments in this area. In general, EDPMA supports the use by CMS of DGs so that CMS can verify that medically necessary services were provided before paying claims. EDPMA also believes that physician use of appropriately structured DGs will promote quality care for all patients, including Medicare beneficiaries. EDPMA supports the use of objective criteria (e.g., "scoring" systems) to avoid confusion for physicians and their coders. Scoring systems help physicians understand, in advance, the standards that will be used by CMS, the OIG and other payers in reviewing claims. Unfortunately, the currently constituted work group for the DGs lacks any representatives from emergency medicine.

Recommendations: EDPMA recommends that as CMS moves forward in this area, CMS should work closely with providers in making sure that any DGs are workable from the provider's perspective and emphasize the use of objective criteria. We believe that emergency medicine should be represented in the DG work group. EDPMA, and particularly its billing company members, may be able to assist CMS in any pilot testing of new DGs.

Use of Physician Assistants

EDPMA is concerned regarding CMS recent policy affecting the flexibility of emergency groups to use physician assistants (PAs) in the ED. The use of PAs is critical to many EDs given the 24-7 demands of hospital EDs and the difficulty recruiting enough physicians. CMS' contractors have denied enrollment in Medicare to PAs that work for ED medical groups on a contractual basis (as opposed to as employees). The refusal to enroll 1099 PAs with their medical group is despite the 1997 Balanced Budget Act ("BBA 97") that states the PA may be either an employee or independent contractor, provided he/she reassigns the Medicare reimbursement to his/her group. CMS' policy appears to be directly contrary to both the Congressional intent to make allied health professionals more accessible and the express provisions of the statute.

CMS has also recently stated that PAs will not be permitted to enroll with Medicare under a medical group provider number if the PA has an equity interest in the medical group. Many state laws permit a PA to have ownership in their medical group, e.g., North Carolina. The ownership of the group must be disclosed on the group's Medicare enrollment application. Medicare contractors have denied group Medicare enrollment where there is a PA with ownership interest in the group.

Recommendations: We believe that CMS should permit entities that employ or contract with PAs to enroll with the Medicare program, as long as the entities are legal entities established in accordance with state law and the services provided by PAs meet the relevant Medicare requirements (e.g., appropriate physician supervision).

HIPAA Privacy Regulations

In December 2000, HHS issued Final Standards for the Privacy of Individually Identifiable Health Information, 42 C.F.R. Parts 160 and 164, (the HIPAA Privacy Regulations). EDPMA shares the concerns of many entities affected by the HIPAA Privacy Regulations. In particular, EDPMA is concerned with reconciling the apparent requirement of obtaining the patient's consent to use or disclose protected health information ("PHI") with the restrictions of EMTALA. Specifically, the OIG/HCFA December 1999 Notice of Special Advisory Bulletin interprets possible delays in patients receiving their medical screening exams as grounds for an EMTALA violation. ED providers are concerned that a requirement to obtain the patient's consent for use or disclosure of PHI could cause delays. Consent forms used in EDs will be longer, and may prompt more patient questions in light of HIPAA. Separately, the "minimum necessary" standard suggests an overly subjective standard for judging whether the use or disclosure was appropriate.

EDPMA is also concerned regarding the timeline for implementation of the HIPAA Privacy Regulations and any modifications that are made before the compliance date. Many EDPMA members could be both covered entities (as providers of physician services) and business associates to covered entities (hospitals). Therefore, EDPMA members are assessing their own compliance strategies as well as working with others to see what other covered entities may be requiring of their business associates.

Recommendations: EDPMA suggests that HHS provide additional guidance to covered entities and issue any modifications to the HIPAA Privacy Regulations as soon as possible so that covered entities can move forward in their compliance strategies.

EDPMA appreciates this opportunity to provide input to the Committee. We would be happy to provide additional materials in any of the areas noted above.

Sincerely,

Edward R. Gaines, III
Chair, EDPMA

Statement of the National Association of Chain Drug Stores, Alexandria, Virginia

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide comments to the Subcommittee on Health of the Committee on Ways and Means on Medicare Regulatory and Contracting Reform. NACDS represents more than 200 chain pharmacy companies that operate almost 35,000 community retail pharmacies. NACDS members provide almost 70 percent of all retail pharmacy prescriptions.

Community retail pharmacies provide prescription services and health care-related products to millions of Medicare and Medicaid recipients each year. For example, many pharmacies provide durable medical equipment (DME) and prescription drugs to Medicare beneficiaries. Pharmacies also provide prescription services to millions of Medicaid recipients. Each program has its own complex set of rules and regulations, which can often result in inefficiency, redundancy, and interfere with the ability of health care providers to deliver quality care.

NACDS supports initiatives by Congress and the Department of Health and Human Services to reform many of these rules and regulations. For example, Congress has considered several bills over the last few years that would begin the process of regulatory reform. The November 2002 report of the Secretary's Advisory Committee on Regulatory Reform suggested ways to reduce some of the burdens imposed on pharmacies—and the patients they serve—by existing HHS regulations, policies, and procedures. NACDS suggests that the following changes be made to existing laws and regulations that would facilitate participation in these programs.

Medicaid Prescription Copays: NACDS supports the use of reasonable cost sharing to encourage the appropriate use of prescription services. In the Medicaid program, however, the law prohibits pharmacies from denying services to recipients who are unable to pay their copayments or coinsurance. Additionally, Federal regulation prohibits states from compensating pharmacies for uncollected copays. For pharmacies, this means that Medicaid prescriptions are often dispensed at an economic loss if the patient cannot or will not pay the copay. As state Medicaid drug budgets escalate, more states are increasing copays, further placing pharmacies at economic risk, and threatening the participation of pharmacies in Medicaid.

The Federal regulation prohibiting states from compensating pharmacies for uncollected prescription copays should be repealed, and states should be required to reimburse pharmacies for these uncollected copays. As a matter of fairness and equity, retail pharmacies should not be forced to bear the burden of uncollected prescription drug copayments. Moreover, CMS should further clarify the circumstances under which an "inability" to pay applies, so that recipients are aware that they must demonstrate true economic hardship in order for the provider to be required to provide the prescription without the copay.

Medicare/Medicaid Coordination of Benefits for Dual Eligibles: Coordination of benefits (COB) is a major issue for NACDS members who participate as Medicare Part B suppliers and as Medicaid providers. Neither Medicare nor Medicaid provides adequate beneficiary information to providers to determine how payors should be billed.

The absence of an online adjudication system in the Medicare program adds to the problem, as most Medicare claims have to be submitted manually. NACDS' goal is to improve cost avoidance efforts without increasing the COB responsibilities of pharmacies. These problems have only worsened because of recent changes in Medicare program requirements for diabetic supplies claims, and Medicaid cost savings recoupment endeavors by some states.

Pharmacy Enrollment as Medicare Suppliers: Many NACDS members are already enrolled in the Medicare program as DMERC suppliers, but are facing problems with completion of enrollment/re-enrollment forms. Consequently, NACDS members may face delayed enrollment or interruption in their status as suppliers.

An unintended consequence is interruption of service to Medicare beneficiaries. The 855S form requires suppliers to submit information and documentation that have not always been necessary for enrollment using the old enrollment applications. For many items, extensive paperwork and disclosure of specific information is required.

Completion of the application is compounded for members that have hundreds or thousands of stores, and are required to complete a separate application for each of their individual stores—despite the fact that most of the information is identical for each of the stores. The application has resulted in the submission of hundreds of thousands of pages of information that could easily be formatted electronically and submitted as a single file. This would reduce the overwhelming paperwork burden that Nation Supplier Clearinghouse (NSC) will encounter when reviewing the applications. On occasion, NSC and CMS have agreed to waive certain requirements, but this has been on a case-by-case basis, and only after numerous phone calls to both NSC and CMS. Both CMS and suppliers would benefit from an overall streamlined application process and acceptance of a uniform documentation standard.

Medicare Diabetes Education and Training Program: Under the 1997 BBA law creating this program, Medicare "suppliers" such as pharmacies are able to provide diabetes education and training services to Medicare beneficiaries. In fact, several NACDS members have received American Diabetes Association (ADA) accreditation for their Medicare diabetes education programs.

However, there are two operational obstacles to broader pharmacy participation. First, there are other diabetes education and training programs that meet the same qualifications and standards as the ADA program, and pharmacies should also be able to obtain accreditation if they complete these other programs. In addition, some members continue to have problems obtaining provider numbers from Medicare to bill for the services they provide. NACDS has determined that one barrier in obtaining provider numbers is the contractors' misunderstanding of pharmacy participation. NACDS will work with CMS to raise contractors' understanding of this issue, and will work with Members of Congress to assure that the program is implemented consistent with Congressional intent.

HIPAA Privacy Protections and Administrative Simplification: To assure maximum patient privacy, as well as administrative simplification in the processing of prescription drug claims, HHS should initiate rulemaking to adopt the Community Pharmacy Based Pharmacy Claims Transaction Standard rather than the current standard that is set to be used under HIPAA, the NCPDP Version 5.1 standard. The NCPDP standard does not assure patient privacy because it still contains many fields for "optional" patient information.

That is, the insurance company or pharmacy benefit manager (PBM) can request this information from the pharmacy—such as address or phone number—this is not necessary to process the prescription claim, and can use this information for purposes unrelated to health care, such as marketing. The pharmacy, which does not want to disclose this information, may have no choice if the payor will not pay the claim without this information.

Moreover, the fact that different payors may request different information for different optional fields can result in several different pharmacy transaction standards, rather than one standard, which was the goal of HIPAA administrative simplification.

In order for beneficiaries to receive the best possible quality of care, all providers, including pharmacies, should be relieved of the burdens associated with participating in federal health care programs. HHS should work with community pharmacy to adopt many of the recommendations made here regarding participation in Medicare and Medicaid. Additionally, Congress should work to address those administrative burdens that require statutory corrections. We appreciate the opportunity to submit this statement for the record.

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